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**UNITED STATES DISTRICT COURT  
 SOUTHERN DISTRICT OF NEW YORK**

SOUTHERN ILLINOIS LABORERS' AND  
 EMPLOYERS HEALTH AND WELFARE )  
 FUND; NECA-IBEW WELFARE TRUST )  
 FUND; MIDWESTERN TEAMSTERS )  
 HEALTH AND WELFARE FUND; THE )  
 WELFARE FUND OF TEAMSTERS LOCAL )  
 UNION 863; PLUMBERS & PIPEFITTERS )  
 LOCAL UNION 630 WELFARE TRUST )  
 FUND; CLEVELAND BAKERS AND )  
 TEAMSTERS HEALTH AND WELFARE )  
 FUND; ELECTRICAL WORKERS BENEFIT )  
 TRUST FUND; FIRE & POLICE RETIREE )  
 HEALTH CARE FUND, SAN ANTONIO, )  
 LABORERS' DISTRICT COUNCIL )  
 BUILDING AND CONSTRUCTION )  
 HEALTH AND WELFARE FUND; )  
 LABORERS' DISTRICT COUNCIL HEAVY )  
 AND HIGHWAY UTILITY HEALTH AND )  
 WELFARE FUND, and NEW YORK CITY )  
 POLICE SERGEANTS BENEVOLENT )  
 ASSOCIATION HEALTH & WELFARE )  
 FUNDS, individually, and on behalf of all )  
 others similarly situated, )

**No. 08cv5175 (DAB)**

Plaintiffs,

v.

PFIZER INC.,

Defendant.

**DECLARATION OF MARK S. CHEFFO IN SUPPORT OF DEFENDANT PFIZER  
 INC'S MOTION FOR RECONSIDERATION OF MINUTE ORDER OF MAY 22, 2008**

MARK S. CHEFFO, an attorney duly admitted to practice before this Court, hereby declares, under penalty of perjury, as follows:

1. I am a member of the bar of this Court and of the firm of Skadden, Arps, Slate, Meagher & Flom LLP, attorneys for Defendant Pfizer Inc in the above-captioned matter.

2. I respectfully submit this declaration in support of Defendant Pfizer Inc's Motion for Reconsideration of the Order of May 22, 2008.

3. Attached hereto are true and correct copies of the following documents:

**Exhibit A** Minute Order (Darrah, J.), filed May 22, 2008 [D.E. 213]<sup>1</sup>

**Exhibit B** Memorandum Opinion and Order (Brown, M.J.), filed November 14, 2007 [D.E. 166]

**Exhibit C** Memorandum Opinion and Order (Brown, M.J.), filed December 21, 2007 [D.E. 185]

**Exhibit D** Letter to the Honorable John W. Darrah from Edward Crane, dated April 8, 2008

**Exhibit E** Class Action Complaint, filed April 3, 2006 [D.E. 1]

**Exhibit F** Amended Class Action Complaint, filed December 11, 2006 [D.E. 45]

**Exhibit G** Defendant Pfizer Inc's Memorandum of Law in Support of Its Motion to Compel Plaintiffs to Provide Proper Responses to Interrogatories and Requests for Production of Documents, without exhibits, filed April 30, 2007 [D.E. 78]

**Exhibit H** Transcript of Continued Hearing on Motions Before The Honorable Magistrate Judge Geraldine Soat Brown, heard June 13, 2007 [D.E. 95]

**Exhibit I** Minute Order (Brown, M.J.), filed June 13, 2007 [D.E. 92]

**Exhibit J** Minute Order (Brown, M.J.), filed August 28, 2007 [D.E. 115]

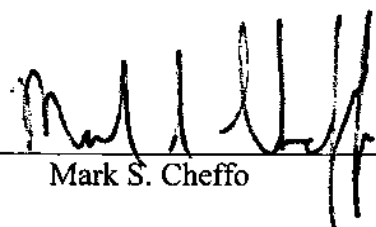
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<sup>1</sup> "D.E. \_\_\_\_" refers to the docket entry number on the docket of the transferor court, the Northern District of Illinois.

- Exhibit K** Plaintiffs' Memorandum of Law in Support of Plaintiffs' Motion to Modify Discovery, without exhibits, filed September 6, 2007 [D.E. 131]
- Exhibit L** Pfizer's Opposition to Plaintiffs' Motion to Modify Discovery, without exhibits, filed September 19, 2007 [D.E. 139]
- Exhibit M** Minute Order (Brown, M.J.), filed September 26, 2007 [D.E. 144]
- Exhibit N** Transcript of Proceedings Before The Honorable Geraldine Soat Brown, heard September 26, 2007
- Exhibit O** Minute Order (Brown, M.J.), filed December 14, 2007 [D.E. 180]
- Exhibit P** Plaintiffs' Amended Objections to Magistrate Brown's Order Dated November 14, 2007 Denying Plaintiffs' Motion to Modify Discovery, without exhibits, filed November 29, 2007 [D.E. 173]
- Exhibit Q** Defendant Pfizer Inc's Opposition to Plaintiffs' Amended Objections To Magistrate Judge Brown's Order Dated November 14, 2007 Denying Plaintiffs' Motion to Modify Discovery, without exhibits, filed December 17, 2007 [D.E. 181]
- Exhibit R** Plaintiffs' Reply in Further Support of Their Amended Objections to Magistrate Judge Brown's Order Dated November 14, 2007 Denying Plaintiffs' Motion to Modify Discovery, without exhibits, filed December 27, 2007 [D.E. 188]
- Exhibit S** Pfizer Inc's Motion to Compel Plaintiffs to Provide Documents, Unredacted Claims Records, and Responses Concerning Pfizer's Proprietary Materials, without exhibits, filed September 7, 2007 [D.E. 133]
- Exhibit T** Plaintiffs' Opposition to Pfizer's Motion to Compel Plaintiffs to Provide Documents, Unredacted Claims Records, and Responses Concerning Pfizer's Proprietary Materials, filed September 19, 2007 [D.E. 140]
- Exhibit U** Defendant Pfizer Inc's Opposition to Plaintiffs' Objections to Magistrate Judge Brown's Order Dated December 21, 2007 Granting Pfizer's Motion to Compel, filed January 24, 2008 [D.E. 202]

- Exhibit V** Pfizer Inc's Reply in Further Support of Its Motion to Compel Plaintiffs to Provide Documents, Unredacted Claims Records, and Responses Concerning Pfizer's Proprietary Materials, filed September 21, 2007 [D.E. 141]
- Exhibit W** Stipulation and Order for Protection of Confidential Information, filed December 14, 2006 [D.E. 48]
- Exhibit X** Plaintiffs' Objections to Magistrate Judge Brown's Order Dated December 21, 2007 Granting Pfizer's Motion to Compel, without exhibits, filed January 15, 2008 [D.E. 196]

Dated: New York, New York  
June 6, 2008

  
Mark S. Cheffo

# **EXHIBIT A**

# United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	John W. Darrah	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	06 C 1818	DATE	5/22/2008
CASE TITLE	Southern Illinois Laborers' and Employers Heath and Welfare Trust Fund, et al. v. Pfizer, Inc.		

## DOCKET ENTRY TEXT

Plaintiffs' objections to the November 14, 2007 order are sustained [173]. The order of November 14, 2007 [165] is set aside. Plaintiffs' motion to modify discovery [136] is granted. Plaintiffs are not required to provide medical information from individual plan participants. Plaintiffs' objections to the December 21, 2007 order [196] are sustained. The order of December 21, 2007 [185] is set aside; Plaintiffs are not required to comply with that order. Status hearing set for 5/29/08 at 9:00 a.m.

■ [ For further details see text below.]

Docketing to mail notices.

## STATEMENT

Before the Court are Plaintiffs' objections to Magistrate Judge Brown's Order of November 14, 2007, denying Plaintiffs' motion to modify discovery, and Plaintiffs' objections to Magistrate Judge Brown's Order of December 21, 2007, granting Defendant's motion to compel.

Plaintiffs, eleven ERISA benefit funds, alleged in their First Amended Complaint ("F.A.C.") that they have been harmed by Defendant's improper marketing of its medication, Lipitor, causing Plaintiffs to pay for "off-label" Lipitor prescriptions.<sup>1</sup> Defendant served interrogatories on Plaintiffs, asking that Plaintiffs identify each off-label Lipitor prescription for which Plaintiffs paid or provided reimbursement.<sup>2</sup> The interrogatory essentially requires Plaintiffs to collect the medical records of every plan participant who was prescribed Lipitor and examine those records to determine whether the prescription was for an off-label use. On August 28, 2007, Magistrate Judge Brown ordered Plaintiffs to answer Defendant's interrogatory.

On September 3, 2007, Plaintiffs were given leave to file, and did file, their Second Amended Complaint ("SAC"). In amending their complaint, Plaintiffs sought to avoid the discovery burden imposed by the August 28, 2007 order. In the SAC, Plaintiffs altered their theory of liability, claiming that they were harmed by Defendant's off-label marketing due to the resulting increased prices for Lipitor, rather than suffering direct harm by being obligated to pay for off-label prescriptions. Plaintiffs moved to modify discovery; and on November 14, 2007, Magistrate Judge Brown denied that motion and ordered Plaintiffs to comply with the August 28, 2007 order. Plaintiffs object to the November 14, 2007 order.

On September 7, 2007, Defendant moved to compel production of a number of documents and an answer to a single interrogatory regarding Plaintiffs' acquisition of Defendant's proprietary documents. On December 21, 2007, Magistrate Judge Brown granted Defendant's motion and ordered Plaintiffs to comply with the discovery requests. Plaintiffs object to this order to the extent that it compels production of documents that are not in Plaintiffs' possession, custody or control and to the extent it compels disclosure of participant-specific information.

## STATEMENT

Rule 72(a) of the Federal Rules of Civil Procedure provides that a district judge "shall modify or set aside any portion of a magistrate judge's order found to be clearly erroneous or contrary to law." Fed. R. Civ. P. 72(a). Magistrate Judge Brown found that the information sought by Defendant was within the scope of discovery under Rule 26 and did not pose an undue burden on Plaintiffs.

With respect to the November 14, 2007 order, Plaintiffs argue that under the SAC, the identification of specific off-label prescriptions is no longer discoverable under Rule 26(b)(1) because it is not relevant to any claim or defense of any party and is not reasonably calculated to lead to the discovery of admissible evidence. Plaintiffs argue that whether they paid for off-label prescriptions is no longer relevant under the theory of damages advanced in the SAC.

Moreover, Plaintiffs make a convincing argument that the relevance of the specific information sought by Defendant is outweighed by the burden to Plaintiffs of producing the information. Rule 26(b)(2) of the Federal Rules of Civil Procedure provides that discovery may be limited if "the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(2). Plaintiffs assert that to gather the information sought, they would have to engage in thousands of communications with plan participants and their physicians to request the participants' medical records. Plaintiffs have attempted to gather a subset of the requested information; and their efforts have been met with severe difficulties, including unresponsive physicians and participants and reluctance on the part of physicians to divulge the contents of their patients' medical records. There is also a significant burden to the participants whose medical records are sought in terms of loss of privacy rights.

Balanced against this burden is the relatively small evidentiary value of the information. Plaintiffs intend to prove their case by the use of Defendant's own documents, commercially available data, econometric modeling and expert testimony. While the number of plan participants is large in terms of the discovery sought, there has been no assertion that a survey of the prescriptions paid for by Plaintiffs would be a valid statistical sample that could be used as evidence to rebut Plaintiffs' nationwide data.

Therefore, the burden imposed by the August 28, 2007 clearly outweighs the likely benefit of the discovery. Magistrate Judge Brown's order of November 14, 2007 is set aside. Plaintiffs motion to modify discovery is granted. Plaintiffs are not required to provide medical information from individual plan participants.

With respect to the December 21, 2007 order, Plaintiffs first argue that Magistrate Judge Brown erred by relieving Defendant of its burden to show Plaintiffs' possession of the documents sought. A party that brings a motion to compel has the burden of showing that the nonmoving party is in control of the requested documents. *Sparks Tune-up Centers, Inc. v. Panchevre*, 1991 WL 101667 at \*3 (N.D. Ill. 1991) (citing *Norman v. Young*, 422 F.2d 470, 473 (10th Cir. 1970); *Technical Concepts, L.P. v. Continental Manufacturing Company*, 262119 WL at \*1 (N.D. Ill. 1994). The December 21, 2007 order does not address this burden but, rather, orders Plaintiffs to produce documents that can be "expected" to be in their possession. Thus, it was error to relieve Defendant of the burden of showing Plaintiffs' control over the requested documents.

Plaintiffs' second basis for their objection to the December 21, 2007 order is that it also fails to balance the burden imposed by the discovery against the relevance of the information sought. Plaintiffs argue that the disclosure of patient-specific information is burdensome for Plaintiffs to produce, is a burden to third parties whose privacy is violated and has minimal, if any, relevance to Plaintiffs' claims. As discussed above, patient-specific information has little relevance to Plaintiffs' claims, as revised in the SAC. Plaintiffs have also shown, through their attempts to date to obtain some of this information, that the collection of the medical records sought by Defendant is extremely burdensome. Balancing the burden of producing this information against its relevance, such discovery is not warranted.

Therefore, the December 21, 2007 order is set aside. Plaintiffs are not required to comply with that order.

Case 1:06-cv-01181-SHS Document 13-2 Filed 05/28/11 Page 3 of 4  
1. An "off-label" use is one that is contrary to the Food and Drug Administration approved uses for the drug.

2. Plaintiffs are employee benefit funds that cover the cost of health care for their participants, including the costs of medically necessary drugs.

## **EXHIBIT B**

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

SOUTHERN ILLINOIS LABORERS' AND	)	
EMPLOYERS HEALTH AND WELFARE	)	
FUND; NECA-IBEW WELFARE TRUST	)	
FUND; MIDWESTERN TEAMSTERS	)	
HEALTH AND WELFARE FUND; THE	)	Case No. 06 C 1818
WELFARE FUND OF TEAMSTERS	)	
LOCAL UNION 863; PLUMBERS &	)	
PIPEFITTERS LOCAL UNION 630	)	Judge John W. Darrah
WELFARE TRUST FUND; CLEVELAND	)	
BAKERS AND TEAMSTERS HEALTH	)	Magistrate Judge Geraldine Soat
AND WELFARE FUND; ELECTRICAL	)	Brown
WORKERS BENEFIT TRUST FUND; FIRE	)	
& POLICE RETIREE HEALTH CARE	)	
FUND, SAN ANTONIO, LABORERS'	)	
DISTRICT COUNSEL BUILDING AND	)	
CONSTRUCTION HEALTH AND	)	
WELFARE FUND; LABORERS'	)	
DISTRICT COUNSEL HEAVY AND	)	
HIGHWAY UTILITY HEALTH AND	)	
WELFARE FUND, and NEW YORK CITY	)	
POLICE SERGEANTS BENEVOLENT	)	
ASSOCIATION HEALTH & WELFARE	)	
FUNDS, individually, and on behalf of all	)	
others similarly situated,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
PFIZER INC.,	)	
	)	
Defendant.	)	

**MEMORANDUM OPINION AND ORDER**

Geraldine Soat Brown, Magistrate Judge

Before the court is Plaintiffs' Motion to Modify Discovery. [Dkt 136.] For the reasons set

out below, the motion is denied.

### BACKGROUND

In this action, eleven ERISA benefit funds (“Plaintiffs”) claim that defendant Pfizer, Inc. (“Pfizer”) improperly marketed the medication Lipitor for “off-label” uses. (Am. Compl. ¶ 3.) [Dkt 45.] After the case was referred to this court for discovery, the parties described the claims as follows:

Plaintiffs allege that Pfizer marketed Lipitor for an unapproved use - - cholesterol reduction in moderate risk patients . . . . Plaintiffs claim, that as a result, they paid for unwarranted Lipitor prescriptions. . . .

(Jt. Initial Status Report ¶ 1.) [Dkt 88.] Plaintiffs’ claims are brought on behalf on themselves and other “third-party/payors . . . that paid any portion of the purchase price for Lipitor” during the Class period, January 1, 2002 to the present. (Second Am. Comp. ¶ 1.) [Dkt 116, 127.]<sup>1</sup> The District Judge has set discovery to close on March 31, 2008. [Dkt 49.]

In June 2006, Pfizer served interrogatories on Plaintiffs, asking, *inter alia*, that they “[i]dentify each prescription of Lipitor for an off-label purpose as defined in the Complaint for which you paid or provided reimbursement.” [Dkt 78-3, Interrog. No. 3.] After a hearing on Pfizer’s motion to compel Plaintiffs to answer Pfizer’s discovery, this court held that the information sought by the interrogatory is discoverable, but allowed Plaintiffs to begin responding by naming a single Plaintiff fund that would provide its information. Specifically, Plaintiffs were ordered to identify by August 20, 2007, each Lipitor prescription written for an allegedly improper off-label

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<sup>1</sup> The Second Amended Complaint was filed under seal. No motion for class certification has yet been filed.

purpose that was paid for by the selected Plaintiff fund. [Dkt 98.]

At a continued hearing on discovery motions on August 28, 2007, Pfizer's counsel reported, and Plaintiffs' counsel admitted, that Plaintiffs had not identified any improper prescriptions, but rather had identified and provided information about four (or possibly six) persons. (Pls.' Reply Supp. Mot. Modify Discovery, Ex. A, Tr. Aug. 28, 2007 at 5, 13-14.) [Dkt 143.] In Pfizer's view, the medical profiles of those persons do not show that prescribing Lipitor for them was improper. (*Id.* at 8.) Plaintiffs' counsel responded that the selected fund had only obtained fifty sets of medical records, and that the actual number of off-label prescriptions would be higher. (*Id.* at 27.) At the conclusion of the hearing, this court ordered each of the Plaintiffs to answer Interrogatory No. 3. [Dkt 115.]

At that hearing, Plaintiffs' counsel announced that Plaintiffs would be seeking leave to file a Second Amended Complaint, changing the theory of damages. (Pls.' Reply at 18-19.) He admitted that the change was as a result of the difficulty in identifying improper prescriptions. (*Id.* at 19.) Subsequently, Plaintiffs were given leave to file their Second Amended Complaint. [Dkt 126.] Pfizer's motion to dismiss that Second Amended Complaint is pending before the District Judge. [Dkt 153.]

Plaintiffs' present Motion to Modify Discovery asks that Plaintiffs be relieved of their obligation to comply with the August 28, 2007 Order. Plaintiffs assert that the Second Amended Complaint makes their compliance unnecessary because Plaintiffs' theory of damages has changed. According to Plaintiffs, the Second Amended Complaint:

does not allege that individual Plaintiffs were duped into paying for specific off-label prescriptions because of a fraudulent marketing campaign. Rather, the SAC [Second Amended Complaint] alleges that Pfizer's off-label or fraudulent marketing drove demand up and increased the price of Lipitor.

(Pls.' Mem. Supp. Mot. at 5.) [Dkt 131.] Plaintiffs intend to prove damages with "commercially available data, Pfizer's own documents produced in discovery, third-party documents produced by Plaintiffs' subpoenae" and expert statistical modeling. (*Id.* at 2.) Pfizer objects to the motion and argues that information about allegedly improper prescriptions remains discoverable under the Second Amended Complaint. (Defs.' Opp'n Pls.' Mot.) [Dkt 139.]

### DISCUSSION

Fifteen months after filing the initial Complaint in this case, Plaintiffs filed a Second Amended Complaint, arguing that they had changed their damage model. The reason for the change, Plaintiffs admit, is the difficulty of pursuing their original damage theory. The issue on the present motion is whether that change justifies relieving Plaintiffs of this court's previous discovery order, either because the information sought is now beyond the scope of discovery or because producing the information is unduly burdensome to the Plaintiffs.

This court agrees with Pfizer that information about the allegedly improper prescriptions for which Plaintiffs paid remains discoverable under the Second Amended Complaint, and that production of the information is not unduly burdensome.

1. The information is within the scope of discovery.

"Parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party . . . . Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1).

Here, the Second Amended Complaint continues the allegations that Plaintiffs paid for improper prescriptions. In moving for leave to file their Second Amended Complaint, Plaintiffs argued that they are “third-party payors who paid for an increased number of prescriptions for Lipitor resulting from Pfizer’s illegal marketing practices . . . .” (Pls.’ Mem. Supp. Mot. Leave File Second Am. Compl. at 2.) [Dkt 113-3.] Contrary to Plaintiffs’ assertions to this court in their present motion, the Second Amended Complaint does, in fact, allege that a primary component of Pfizer’s allegedly illegal scheme has been an effort to expand the market for Lipitor by promoting the off-label use of the drug, which “resulted in an artificially increased number of Lipitor prescriptions *for which the Plaintiff Funds were required to pay . . . .*” (Second Am. Compl. ¶¶ 3-4, emphasis added.) Plaintiffs further claim that, “Plaintiffs paid improperly inflated prices for Lipitor and *for an increased number of Lipitor prescriptions* generated through Pfizer’s illegal marketing tactics.” (*Id.* ¶ 5, emphasis added.)

Each of the Plaintiffs alleges not only that it paid an inflated price for Lipitor but also that it paid for “an increased number of Lipitor prescriptions generated through Pfizer’s illegal marketing campaign.” (*Id.* ¶¶ 8-18.)

Thus, the claim that Plaintiffs were injured because they paid for unwarranted Lipitor prescriptions did not disappear with the filing of the Second Amended Complaint. Plaintiffs continue to allege that Pfizer’s alleged scheme caused Lipitor to be prescribed to persons for whom the drug is not medically necessary or indicated for use, costing the third-party payors “billions of dollars.” (*Id.* ¶ 110.) Although Plaintiffs’ damage calculation is now based on a theory that Plaintiffs had to pay an artificially inflated price for Lipitor prescriptions (*id.* ¶¶ 6, 178), the underlying premise is that the price inflation was the result of fraudulently increased demand. (*Id.*

¶ 5.) The cause of Plaintiffs' injuries is alleged to have been that Plaintiffs incurred additional costs resulting from paying for the increased number of Lipitor prescriptions, as well as paying for Lipitor at an artificially increased price. (*Id.* ¶ 220.)

In light of the allegations of the Second Amended Complaint, the scope of discover plainly includes not only the total number of Lipitor prescriptions for which each Plaintiff fund paid as well as the amount paid for those, but also the identity of the prescriptions that Plaintiffs claim were the "increased" prescriptions for which each Plaintiff fund paid that were caused by Pfizer's alleged marketing scheme.

2. The discovery does not pose an undue burden on Plaintiffs.

Plaintiffs argue that obtaining the medical information required to determine which of the Lipitor prescriptions were "unnecessary" or "unwarranted" imposes an undue burden on them. That argument is rejected, for a number of reasons.

First, this court rejected that argument in July 2007 when it ordered Plaintiffs to obtain the information, starting with a fund of Plaintiffs' selection. As late as September 5, 2007, Plaintiffs said they planned to identify the prescriptions that were the result of improper marketing by identifying each participant who received prescriptions for Lipitor, and by reviewing the participant's medical records, to determine if the Lipitor prescription was for off-label uses. (Def.'s Opp'n Pls.' Mot., Ex. A at Request No. 13.)

Now, however, Plaintiffs claim that they have no intention of using the participants' medical records to prove their case or to calculate damages. (Pls.' Mem. at 7.) As discussed above, the allegations of the Second Amended Complaint contain substantially the same claims that Plaintiffs

paid for an unnecessarily and artificially increased number of prescriptions. Pfizer has a right to discover the information that would confirm or refute those allegations, whether or not Plaintiffs are interested in using that information in their own case.

Plaintiffs have not demonstrated that it is impossible to produce the information about what prescriptions they paid for and which of those they consider to have been the unnecessary result of improper marketing. They argue only that it is burdensome. They claim that there are over a thousand Lipitor-taking participants collectively in the Plaintiff funds, and that answering the interrogatory requires them to assemble information from “not always amenable third parties.” (*Id.* at 3.) Pfizer asserts that Plaintiffs have a contractual right to obtain information about the participants and the medical benefits for which the Plaintiff funds paid. (Def.’s Opp’n Pls.’ Mot. at 11.) Plaintiffs’ Reply did not dispute that assertion.

In fact, Plaintiffs are ERISA benefit funds of which the participants are the beneficiaries. The trustees of the Plaintiff funds are fiduciaries of the beneficiaries, and the damages to be recovered, if any, become property of the funds to be held in trust for the beneficiaries.

In considering whether the burden is “undue,” the court may consider whether “the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties’ resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues.” Fed. R. Civ. P. 26(b)(2)(C)(iii). There is no doubt that Plaintiffs here seek a huge recovery, a return of all of the money obtained by Pfizer as a result of the alleged scheme. (Second Am. Compl. ¶ 229.) They estimate Pfizer’s unlawful sales of Lipitor during the Class Period to be in the tens of *billions* of dollars. (*Id.* ¶ 7.)

Given the large sums of money that Plaintiffs seek, it is understandable that Pfizer wants to know whether Plaintiffs' own experiences support their claims. Particularly striking is the fact that the fund selected by the Plaintiffs to provide the first answer to Pfizer's interrogatory identified at most 6 *individuals*. As this court expressed at the hearing on August 28, 2007, the parties' judgments about how to proceed, including, for example, whether settlement is possible, depend on getting a firm grasp of the facts behind the allegations.

Plaintiffs were served with Pfizer's interrogatory at issue well over a year ago, and had a plan as to how to obtain the information in September 2007. The court finds that the burden of responding is not undue.

#### CONCLUSION

Plaintiffs' Motion to Modify Discovery is denied. Plaintiffs shall comply fully with this court's order of August 28, 2007. In view of the limited time remaining for discovery, Plaintiffs' answers to Pfizer's Interrogatory No. 3 shall be served on a rolling basis as each Plaintiff fund obtains the information, with full and complete sworn answers served by all Plaintiffs no later than December 21, 2007.

IT IS SO ORDERED.



Geraldine Soat Brown  
United States Magistrate Judge

November 14, 2007

## **EXHIBIT C**

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

**SOUTHERN ILLINOIS LABORERS' AND  
EMPLOYERS HEALTH AND WELFARE  
FUND; NECA-IBEW WELFARE TRUST  
FUND; MIDWESTERN TEAMSTERS  
HEALTH AND WELFARE FUND; THE  
WELFARE FUND OF TEAMSTERS  
LOCAL UNION 863; PLUMBERS &  
PIPEFITTERS LOCAL UNION 630  
WELFARE TRUST FUND; CLEVELAND  
BAKERS AND TEAMSTERS HEALTH  
AND WELFARE FUND; ELECTRICAL  
WORKERS BENEFIT TRUST FUND; FIRE  
& POLICE RETIREE HEALTH CARE  
FUND, SAN ANTONIO, LABORERS'  
DISTRICT COUNSEL BUILDING AND  
CONSTRUCTION HEALTH AND  
WELFARE FUND; LABORERS'  
DISTRICT COUNSEL HEAVY AND  
HIGHWAY UTILITY HEALTH AND  
WELFARE FUND, and NEW YORK CITY  
POLICE SERGEANTS BENEVOLENT  
ASSOCIATION HEALTH & WELFARE  
FUNDS, individually, and on behalf of all  
others similarly situated,**

**Plaintiffs,**

**v.**

**PFIZER INC.,**

**Defendant.**

**Case No. 06 C 1818**

**Judge John W. Darrah**

**Magistrate Judge Geraldine Soat  
Brown**

**MEMORANDUM OPINION AND ORDER**

**Geraldine Soat Brown, Magistrate Judge**

Before the court is Pfizer, Inc.'s Motion to Compel Plaintiffs to Provide Documents.

Unredacted Claims Records, and Responses Concerning Pfizer's Proprietary Materials ("Pfizer's Mot."). [Dkt 133.] For the reasons set out below, the motion is granted.

### BACKGROUND

The background of this case was set out in this court's prior opinion denying Plaintiffs' Motion to Modify Discovery. (Memorandum Opinion and Order ("November 14 Order").) [Dkt 166.] In summary, the plaintiffs are eleven healthcare benefit funds (collectively, "Plaintiffs") that pay for prescription medications for their members and those members' dependants. Plaintiffs' Second Amended Complaint alleges that defendant Pfizer conducted an illegal marketing scheme for its drug Lipitor that resulted in an artificially increased number of Lipitor prescriptions for which Plaintiffs were required to pay at improperly inflated prices. (Second Am. Compl. ¶¶ 3-5.) [Dkt 116.] Pfizer's motion to dismiss the Second Amended Complaint [dkt 153] is currently pending. The District Judge has extended discovery to March 31, 2008. [Dkt 176.]

Plaintiffs filed objections to this court's November 14 Order, which are still pending before the District Judge. [Dkt 173.] Subsequently, the parties filed a Joint Motion, asking that Plaintiffs' compliance with the November 14 Order be stayed because of the pending motions before the District Judge ("Jt. Mot."). [Dkt 177.] This court granted that motion, staying Plaintiffs' compliance with the November 14 Order until ten days after the District Court's final ruling on Plaintiffs' objections. [Dkt 180.]

In the present motion, Pfizer seeks documents and an answer to one interrogatory. Plaintiffs responded, arguing that the motion should be denied ("Pls.' Opp'n" [dkt 140]), and Pfizer filed a reply ("Pfizer's Reply" [dkt 141]). According to their Joint Motion to stay the November 14 Order,

the parties believe that a ruling on the present motion is necessary, notwithstanding the events described above and their own agreed “informal stay of discovery.” (Jt. Mot. at 5.)

## ANALYSIS

### I. Interrogatory No. 1 of Pfizer’s Fourth Set of Interrogatories.

According to Pfizer, Plaintiffs somehow acquired “over 2,200 pages, along with audio and video cassette tapes and CDS, of internal, confidential, proprietary, and apparently misappropriated, Pfizer materials that [Plaintiffs] referenced in their pleadings and produced to Pfizer during discovery.” (Pfizer’s Mot. at 12.) Pfizer propounded an interrogatory to one of the Plaintiff Funds, asking it to “identify the individual or individuals who provided to [Plaintiffs] documents and other items bates stamped as PLCONS 000001-002269, and describe the circumstances under which these documents and materials were given or shown to [Plaintiffs].” (Pfizer’s Mot., Ex. E at 3.) The Plaintiff Fund objected to the interrogatory on the ground that the information is protected work product. (*Id.*)<sup>1</sup> In response to Pfizer’s motion, Plaintiffs argue that their counsel interviewed those

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<sup>1</sup> The Plaintiff Fund further objected to Interrogatory 1 on the ground that it called for information that was neither relevant nor reasonably calculated to lead to the discovery of relevant evidence. (Pfizer’s Mot., Ex. E at 3.) Because Plaintiffs did not develop that argument in their Opposition (*see* Pls.’ Opp’n at 11-13), and the court finds that the information meets the standard of relevance under Rule 26(b)(1) in any event, that objection is overruled.

Additionally, the Plaintiff Fund prefaced its Responses and Objections to Pfizer’s interrogatories with a number of so-called “General Objections.” (Pfizer’s Mot., Ex. E at 2.) However, it is well-settled that general objections are insufficient to voice a successful objection. *See, e.g., St. Paul Reinsurance Co., Ltd. v. Commercial Financial Corp.*, 198 F.R.D. 508, 511-12 (N.D. Iowa, 2000) (collecting cases). Fed. R. Civ. P. 33(b)(4) requires that “[a]ll grounds for an objection to an interrogatory shall be stated with specificity.” Rule 33(b)(1) provides that “the objecting party shall state the reasons for objection and shall answer to the extent the interrogatory is not objectionable.” Similarly, Local Rule 33.1 of the Northern District of Illinois requires that “[w]hen objecting to an interrogatory or to the answer to an interrogatory, a party shall set forth the interrogatory or the interrogatories and answer thereto immediately preceding

individuals as part of counsel's pre-suit investigation and that answering Interrogatory 1 would reveal attorney mental impressions and trial strategy, which are protected by the work product doctrine. (Pls.' Opp'n at 12.)

The work product doctrine protects "*documents and tangible things* otherwise discoverable . . . prepared in anticipation of litigation or for trial by or for another party or by or for that other party's representative." Fed. R. Civ. P. 26(b)(3), *emphasis added*. While "the mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of a party concerning the litigation" are protected by the work product doctrine, *id.*, the disclosure of *facts* cannot be precluded simply because the facts were learned by an attorney. *See Hickman v. Taylor*, 329 U.S. 495, 504, 506-07 (1947) (stating that "[a] party clearly cannot refuse to answer interrogatories on the ground that the information sought is solely within the knowledge of his attorney"). *See also* Edna Selan Epstein, *The Attorney-Client Privilege and the Work Product Doctrine* 488 (American Bar Association 4th ed. 2001) (stating that "the work-product protection cannot be asserted to prevent disclosure of the underlying facts, which are discoverable in any adversary proceeding"); 8 Charles Alan Wright, Arthur R. Miller & Richard L. Marcus, *Federal Practice and Procedure: Civil 2d* § 2023 at 330 (2d ed. 1994) (stating that courts consistently hold that the work product concept furnishes no shield against discovery of the persons from whom an attorney has learned facts).<sup>2</sup>

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the objection." In other words, the interrogatory to which the objection is made must be set out, followed by any objection to the interrogatory. Thus, reciting a litany of "General Objections" as a preface, leaving the propounding party and the court to guess which, if any, are applicable to any particular interrogatory, is not authorized or recognized by the Federal Rules of Civil Procedure or the Local Rules of the Northern District of Illinois.

<sup>2</sup>*See also Clark Equip. Co. v. Lift Parts Mfg. Co.*, 1985 WL 2917 at \*7 (N.D. Ill. Oct. 1, 1985) (Holderman, J.) (holding that "[t]he attorney work product privilege *does not* preclude the disclosure of *facts* or the identity of witnesses or documents simply because their existence was

Here, Pfizer is not seeking documents or tangible things that might include reference to Plaintiffs' counsel's strategy, but rather factual information: from whom specific documents were obtained and under what circumstances. As Pfizer argues, the persons who provided the documents are likely to have information relevant to Plaintiffs' claims and may be witnesses in the litigation. (Pfizer's Mot. at 13, 14.) Indeed, information about the source of the documents would likely be part of the authenticating foundation for any use of the documents as evidence. *See* Fed. R. Evid. 901.

In opposition, Plaintiffs cite two California cases in which defendants sought to compel plaintiffs to identify the employees who had provided information that plaintiffs' counsel used to draft the allegations of the complaint. *In re MTI Tech. Corp. Sec. Litig. II*, 2002 WL 32344347 at \*1 (C.D. Cal. June 13, 2002) (Carter, J.) and *In re Ashworth, Inc. Sec. Litig.*, 213 F.R.D. 385, 386 (S.D. Cal. 2002). The courts in those cases interpreted the defendants' interrogatory as seeking in effect the disclosure of plaintiffs' counsel's selection of witnesses to interview. *MTI*, 2002 WL 32344347 at \*3; *Ashworth*, 213 F.R.D. at 388-89. The court in *Ashworth* observed that whether such information was protected work product was "unclear," but concluded that compelling an answer to the interrogatory created "a reasonable possibility" that the identity of persons the plaintiffs' counsel selected to interview "could be ferreted out," and "would necessarily reveal counsel's opinions regarding the relative importance of these witnesses, the highlights of their

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discovered by counsel"); *Stewart v. Gen. Motors Corp.*, 1988 WL 6927 at \*4 (N.D. Ill. Jan. 27, 1988) (Hart, J.) (holding that plaintiff is entitled to learn who has seen a copy of a privileged letter at issue, because "information about sources of information, who has worked on the documents, and who has possessed the documents" is not covered by the work product doctrine); *Patterson v. Burge*, 2007 WL 1317128 at \*2 (N.D. Ill. May 4, 2007) (Brown, M.J.) (compelling plaintiff to testify as to any factual information of which he is aware regarding his case, regardless of whether that information was obtained in the course of his investigations, because "[f]actual information that [a plaintiff] has about [its] case . . . is not protected work product").

testimony/factual knowledge, and would link any future statements by the witnesses with [p]laintiff's counsel's legal theories and conclusions as outlined in the complaint. " *Ashworth*, 213 F.R.D. at 387-89.

In declining to compel the disclosure, the court in *Ashworth* acknowledged that other courts have taken a different view. 213 F.R.D. at 387-88.<sup>3</sup> See, e.g., *In re Theragenics Corp. Secs. Litig.*, 205 F.R.D. 631, 634, 636 (N.D. Ga. 2002) (ordering plaintiffs to disclose the names of individuals upon whom they relied in making allegations in their complaint because "names and addresses of witnesses interviewed by counsel who have knowledge of the facts alleged in the complaint are not protected from disclosure by the work product doctrine"); *Brody v. Zix Corp.*, 2007 WL 1544638 at \*\* 1, 2 (N.D. Tex. May 25, 2007) (Kaplan, M.J.) (compelling plaintiffs to identify several former employees of defendant who were referred to in plaintiffs' complaint as "confidential sources," along with all communications between those sources and plaintiffs or their counsel).

Here, there is no need to resolve that issue because the information sought by Pfizer's interrogatory is plainly different from that involved in the *Ashworth* and *MTI* cases. Identifying the source of specific documents will not reveal the mental processes or litigation strategy of Plaintiffs' counsel. On the contrary, the provenance of the documents is relevant to their admissibility as evidence. Thus, the objection to Interrogatory No. 1 of Pfizer's Fourth Set of Interrogatories is

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<sup>3</sup>Interestingly, the court in *Ashworth* found "unpersuasive" the decision in *American Floral Servs., Inc. v. Florists' Transworld Delivery Assn.*, 107 F.R.D. 258 (N.D. Ill. 1985). *Ashworth*, 213 F.R.D. at 387 n 4. However, the court in *American Floral* drew a distinction between the disclosure that it ordered in that case - - the names of two of defendant's employees who had provided information to plaintiff's counsel to confirm plaintiff's counsel's suspicions about deficiencies in defendant's document production - - and a prior case in which the court had declined to compel plaintiff's counsel to identify the persons counsel had interviewed in the course of preparing the case. *American Floral*, 107 F.R.D. at 261.

overruled, and Plaintiffs must answer that interrogatory.

## **II. Pfizer's document requests.**

### **A. Relevance.**

Pfizer's motion recites a list of scores of document requests that it claims Plaintiffs have either not satisfied or have not satisfied completely. (Pfizer's Mot. at 5-9.) To cite just a few examples, in June 2007, Plaintiffs agreed to produce documents identifying the name of any physician who prescribed Lipitor for an off-label purpose (Doc. Req. 7), documents reflecting payments by Plaintiffs for Lipitor from 2002 to present (Doc. Req. 8), documents reflecting payments by Plaintiffs for Lipitor prescribed for an off-label purpose from 2002 to present (Doc. Req. 9), and contracts between Plaintiffs and any other entity concerning payment for Lipitor for the Plaintiff Funds' participants (Doc. Req. 12). (Pfizer's Mot., Ex. A at 4-6.) According to Pfizer, Plaintiffs have produced nothing in response to Requests 7 and 9, and nothing or incomplete production in response to Requests 8 and 12. (Pfizer's Mot. at 5, 8.)

Plaintiffs' Opposition does not attempt to discuss any individual request. Instead, Plaintiffs make essentially the same two broad-stroke arguments that they made in their Motion to Modify Discovery: First, that "[m]uch of the information Pfizer seeks to compel is no longer relevant" (Pls.' Opp'n at 5); and second, that the requests are unduly burdensome because they seek information not in Plaintiffs' control. (*Id.* at 7.)

Plaintiffs' arguments fall short. To start, although Plaintiffs describe twelve of the Requests as irrelevant under the theory of their Second Amended Complaint (Pls.' Opp'n at 7), that still leaves a multitude of other Requests that are indisputably relevant, even under the Plaintiffs' view

of their Second Amended Complaint. By way of illustration, those include, but are not limited to the following: Documents sufficient to determine the amount of damages alleged (Doc. Req. 10); documents regarding Plaintiffs' initial determination to pay for Lipitor (Doc. Req. 19); documents provided to participants or physicians by Plaintiffs regarding reimbursement or payment for Lipitor (Doc. Req. 21); any statement about Lipitor that Plaintiffs relied upon (Doc. Req. 29); and any Lipitor ad or promotional piece relied upon by Plaintiffs (Doc. Req. 30).

Second, Plaintiffs' argument that discovery about their own experience in reimbursing their participants for Lipitor, and particularly Plaintiffs' payments for allegedly improper prescriptions for off-label purposes, is now irrelevant ignores some of Plaintiffs' own allegations in the Second Amended Complaint. (See Nov. 14 Order at 5-6.) The Second Amended Complaint asserts that Plaintiffs were the victims of a fraudulent marketing scheme by Pfizer for the over-promotion of Lipitor, which, Plaintiffs allege, "increased the demand and expanded the market for Lipitor, artificially driving up Lipitor's price and thereby damaging the Plaintiffs. . . ." (Jt. Mot. at 3.) Additionally, as further described in the November 14 Order, the Second Amended Complaint continues the allegations that Plaintiffs paid for an increased number of Lipitor prescriptions as a result of the scheme. (Nov. 14 Order at 6.) Thus, documents that would demonstrate, for example, the amounts that Plaintiffs paid for Lipitor over time, and whether Plaintiffs actually paid for an increased number of prescriptions of Lipitor as a result of Pfizer's alleged marketing scheme, are well within the scope of discovery under the Federal Rules of Civil Procedure.

Thus, Plaintiffs' current refusal to produce previously-agreed documents on the ground that those documents are now irrelevant is overruled.

B. Burdensomeness.

As was the case with Plaintiffs' Motion to Modify Discovery, Plaintiffs' current objections to production on the basis of burdensomeness are general and lacking in factual support. Plaintiffs complain that they do not "possess or control much of the individual physician and patient information Pfizer seeks." (Pls.' Opp'n at 7-8.) That, of course, begs the question of what information Plaintiffs *do* possess or control. Plaintiffs' Opposition provides the court no affidavits or even descriptions of what information Plaintiffs maintain about the Plans they administer, the benefits they provide, and the prescriptions for which they have paid. Even a cursory review of Pfizer's document requests discloses many categories that can certainly be expected to be in Plaintiffs' possession, custody or control, including but not limited to the following: Documents identifying any accountant retained by Plaintiffs to assist with reimbursement for Lipitor (Doc. Req. 54); documents relating to meetings where a presentation about Lipitor was made to the Plaintiffs or their employees (Doc. Req. 56); any annual or scheduled audit of benefits provided to participants (Doc. Req. 59); any audit of Plaintiffs conducted within the past 5 years (Doc. Req. 62); reports, recommendations or analysis relating to Lipitor that were provided by any consultant to Plaintiffs' trustees (Doc. Req. 64); documents identifying individuals responsible for reviewing claims submitted by participants (Doc. Req. 72).

As for individual patient and physician information, Plaintiffs argue that it was an "enormous burden" to comply with the court's earlier order to produce the off-label Lipitor prescriptions for one Plaintiff Fund. (Pls.' Opp'n at 2.) They further assert that "certain doctors and medical groups" resisted Plaintiffs' efforts to obtain information to comply with the order, citing state privacy laws. (*Id.* at 3.)

There are several problems with Plaintiffs' burdensomeness argument. First, it lacks any evidentiary support in the form of affidavit or declaration providing specifics about such topics as: What records Plaintiffs themselves maintain in the course of administering benefits; whether some or all of the Plaintiffs maintain records of the prescriptions for which they have paid; whether the Plan documents for each Plaintiff Fund contain a cooperation clause (as might be expected) requiring the participants and medical providers obtaining benefits to cooperate with the Funds in seeking reimbursement; how many medical providers refused to produce patient records; and whether the Funds sought participant cooperation to obtain the records, and so on. An objection to producing relevant documents on the basis of burdensomeness must be supported by a factual basis. Counsel's argument in a brief, unsupported by evidence, is not sufficient to sustain a burden of providing evidence. *USA v. Stevens*, 500 F.3d 625, 628-29 (7th Cir. 2007).

Second, Plaintiffs are simply incorrect in arguing that the medical providers were entitled to object on the basis of state privacy laws. (Pls.' Opp'n at 3.) Plaintiffs cite the district court opinion in *National Abortion Federation v. Ashcroft*, 2004 WL 292079 (N.D. Ill. Feb 6, 2004) (Kocoras, C.J.), for the proposition that Illinois' more restrictive medical information disclosure laws controlled over the application of HIPAA. However, while affirming the district court on a different ground, the Seventh Circuit overruled the district court's conclusion on the point Plaintiffs argue:

[W]e agree with the government that the HIPAA regulations do not impose state evidentiary privileges on suits to enforce federal law. Illinois is free to enforce its more stringent medical-records privilege (there is no comparable federal privilege) in suits in state court to enforce state law and, by virtue of an express provision in Fed. R. Evid. 501, in suits in federal court (mainly diversity suits) as well in which state law supplies the rule of decision. But the Illinois privilege does not govern in federal-question suits, such as the suit in the Southern District of New York.

*Northwestern Memorial Hospital v Ashcroft*, 362 F.3d 923, 925 (7th Cir. 2004).

In this case, Plaintiffs invoke federal question jurisdiction under 28 U.S.C. § 1331, based on their claims under the RICO statute, 18 U.S.C. § 1962. (Second Am. Compl. ¶ 22.)<sup>4</sup> Accordingly, Plaintiffs cannot use state law privileges as a justification for refusing to produce documents and information.

The Seventh Circuit affirmed the quashing of the subpoena in the *Ashcroft* case because the probative value of the information was “meager” compared to the invasion of privacy of women whose records were sought and were not in any way involved in the case. 362 F. 3d at 929-30. In this case, the information Pfizer seeks goes directly to the question of whether Plaintiffs paid for more Lipitor prescriptions than necessary and whether Plaintiffs paid too much for Lipitor. That is the heart of Plaintiffs’ claims. Unlike the women whose records were sought in *Ashcroft*, the participants here are the beneficiaries of the Plaintiffs; they will presumably benefit from any recovery obtained in this case. Any concerns about privacy can be dealt with through the Protective Order previously entered in this case.

Finally, as discussed in the November 14 Order, the issue is not whether producing the discovery is a burden; it is whether the burden is “undue” in light of the factors set out in Fed. R. Civ. P. 26(b)(2)(C)(iii). (Nov. 14 Order at 7.) The information is relevant to the issues of both causation and damage. Plaintiffs here are not individuals. They are benefit funds seeking billions of dollars in damages. Plaintiffs have not demonstrated that the burden of production is undue.

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<sup>4</sup>Plaintiffs also allege diversity jurisdiction, but one of the Plaintiffs is a New York City Police Sergeants Fund that also asserts claims on behalf of third-party payors located in New York. (Second Am. Compl. ¶ 1.) Pfizer is a Delaware corporation with its principal place of business in New York (*Id.* ¶ 19), and, thus, is a citizen of both Delaware and New York. 28 U.S.C. § 1332 (c)(1). Accordingly, federal jurisdiction cannot be premised on diversity.

### III. Redaction of information about participants.

According to Pfizer, seven of the Plaintiff Funds have produced information about Lipitor prescriptions for which they paid, but four of those have redacted identifying participant information, such as names and dates of birth. (Pfizer's Mot. at 10.) The Protective Order previously entered by the District Judge with the agreement of the parties specifically identified the "Names of customers or patients" as information that could be designated "Confidential" and held subject to the Protective Order. (Stipulation and Order for Protection of Confidential Information ¶ 2(a).) [Dkt 48.]

Plaintiffs do not argue that the Protective Order is not sufficient or should be modified. Instead, they want to avoid any identification of participants, claiming that Pfizer intends to use the individual participants' information for harassment. (Pls.' Opp'n at 8.) Plaintiffs argue that the individual participants' information is of limited relevance because they -- Plaintiffs -- do not plan to use it in their case. (*Id.* at 9.) However, as discussed above and in the November 14 Order, Pfizer has a right to discovery that will test the validity of Plaintiffs' allegations that they paid for an "artificially increased number of Lipitor prescriptions." (Second Am. Compl. ¶ 4.) Apparently, Pfizer intends to use the medical records of the participants for whom Lipitor was allegedly improperly prescribed to demonstrate that the prescription was not the result of improper marketing, and thus undermine any opinions Plaintiffs' experts may draw about Pfizer's marketing causing an expanded demand and inflated price. (Pfizer's Reply at 11.) The identity of the participant whose Lipitor prescription was paid by Plaintiffs is necessary in order to obtain and relate the medical data.

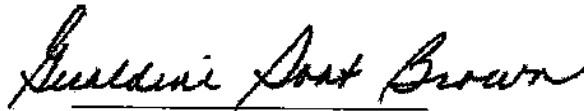
Whether or not the records will support Pfizer's position is not the question at the discovery stage. The information is within the scope of discovery. There is a Protective Order in place to preserve confidentiality. Accordingly, Plaintiffs' objection to providing that information subject to

the Protective Order is overruled.

### CONCLUSION

For the foregoing reasons, Pfizer's Motion to Compel is granted. Plaintiff New York City Police Sergeants Benevolent Association Health & Welfare Funds must serve a sworn answer to Interrogatory 1 no later than January 8, 2008. Plaintiffs must produce responsive documents no later than January 18, 2008.

IT IS SO ORDERED.

A handwritten signature in black ink, reading "Geraldine Soat Brown". The signature is written in a cursive, flowing style.

Geraldine Soat Brown  
United States Magistrate Judge

December 21, 2007

## **EXHIBIT D**

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**VIA HAND DELIVERY**

April 8, 2008

The Honorable John W. Darrah  
United States District Court  
Northern District of Illinois  
Everett McKinley Dirksen Building  
Chambers, Room Number 1288  
219 South Dearborn Street  
Chicago, Illinois 60604

Re: Southern Illinois Laborers et al. v. Pfizer Inc,  
N.D. Ill., C.A. No. 06-CV-1818

Dear Judge Darrah:

I write to bring to the Court's attention a recent decision by the Second Circuit Court of Appeals, *McLaughlin v. Philip Morris USA, Inc.*, — F.3d —, 2008 WL 878627 (2d Cir. Apr. 3, 2008), that bears upon Plaintiffs' pending objections to Judge Brown's two discovery orders in this case. The decision is especially pertinent in light of Plaintiffs' consent to a transfer of this action to the Southern District of New York.

In *McLaughlin*, plaintiffs seeking to represent a nationwide RICO class of cigarette purchasers claimed that defendants' alleged deceptive marketing of "light" cigarettes as a healthier alternative to regular cigarettes "led them to buy Lights in greater quantity than they otherwise would have and at an artificially high price." 2008 WL 878627, at \*1. Similarly, here, Plaintiffs seek to represent a nationwide RICO class and allege that "[a]s a result of Pfizer's illegal, false and misleading marketing and promotion of Lipitor, Plaintiffs paid improperly inflated prices for Lipitor and for an increased number of Lipitor prescriptions." Second Amended Compl., ¶ 5. Judge Brown ordered Plaintiffs to produce prescription-specific information and many other types of documents, which bear upon individual issues of reliance and injury, yet Plaintiffs have objected on grounds that such information is irrelevant.

The decision in *McLaughlin* provides additional, and compelling, support for Judge Brown's rulings. The Second Circuit recognized that the type of discovery Plaintiffs have failed and refused to produce, and that Judge Brown has twice directed them to provide, is, in fact, essential to Plaintiffs' claims, and as such, unquestionably relevant and discoverable. The Second Circuit held that the class certified by Judge Jack B. Weinstein could not be maintained under Rule 23(b)(3) of the Federal Rules because individual issues of reliance and injury – two essential elements of plaintiffs' RICO claims – outweighed issues susceptible to common proof. *See McLaughlin*, 2008 WL 878627, at \*1, 14. In particular, the court repeatedly emphasized that evidence of which, if any, marketing statements each plaintiff saw and relied upon, and each plaintiff's actual out-of-pocket damages, would be critical to their claims, and defendants' defenses, under RICO. The court noted, for example, that "[i]ndividualized proof" of reliance would be

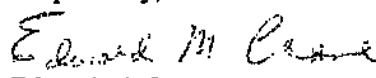
needed to overcome the possibility that a member of the purported class purchased Lights for some reason other than the belief that Lights were a healthier alternative – for example, if a Lights smoker was unaware of that representation, preferred the taste of Lights, or chose Lights as an expression of personal style.

*Id.* at \*4. Similarly, with regard to plaintiffs' price inflation theory of economic loss, it found that "establishing the first link in the causal chain – that defendants' misrepresentation caused an increase in market demand – would require individualized proof, as any number of other factors could have led to this increase." *Id.* at \*6.

Thus, the Second Circuit's decision confirms that information about individual issues of causation, reliance, and injury – such as the Plaintiff-specific and prescription-specific information that Judge Brown has directed Plaintiffs to produce – is plainly relevant to, and critical to the resolution of, Plaintiffs' claims.

Accordingly, we respectfully submit that the Second Circuit's decision further supports denial of Plaintiffs' objections to Judge Brown's discovery orders.

Respectfully,

  
Edward M. Crane

cc: Stephen G. Grygiel, Esq.  
George S. Bellas, Esq.

# **EXHIBIT E**

UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
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**06CV1818**  
**JUDGE DARRAH**  
**MAGISTRATE BROWN**

*Lead Counsel for Plaintiff and Proposed Lead  
Counsel for the Class*

SOUTHERN ILLINOIS LABORERS'  
AND EMPLOYERS HEALTH AND  
WELFARE FUND, NECA-IBEW WELFARE  
TRUST FUND, and MIDWESTERN  
TEAMSTERS HEALTH AND  
WELFARE FUND, individually, and  
On Behalf of All Other Similarly Situated,

Plaintiffs,

v.

PFIZER INC.,

Defendant.

CIVIL ACTION No.

**JURY TRIAL DEMANDED**  
**CLASS ACTION COMPLAINT**

# **Table of Contents**

	<b>Page</b>
I. NATURE OF THE ACTION .....	1
II. Parties.....	2
III. Jurisdiction and Venue.....	4
IV. BACKGROUND .....	4
A. Background On Lipitor.....	4
B. The Food And Drug Administration's Prohibition Of Off-Label Marketing.....	5
C. The ATP III Guidelines .....	7
1. Summary Of The ATP III Guidelines.....	7
2. The Purpose Behind The ATP III Guidelines.....	10
D. Lipitor's On Label Indications.....	12
E. Pfizer's Scheme Defrauds Medicare and Medicaid .....	14
F. Pfizer Defrauds Third-Party Payors.....	16
V. PFIZER'S SCHEME .....	17
A. Pfizer's Scheme Targets A Defined Group of Persons.....	17
B. Pfizer's Illegal Promotion Of Lipitor Targets Pharmacy Benefit Decision Makers, Physicians, And Consumers .....	19
1. Pfizer Illegally Promotes The Off-Label Use Of Lipitor To Pharmacy Benefit Decision Makers.....	19
2. Pfizer Illegally Induces Physicians To Prescribe Lipitor For Off-Label Uses.....	22
3. Pfizer Illegally Promotes Lipitor's Off-Label Use To Consumers.....	27
C. Pfizer's Scheme To Promote The Off-Label Use Of Lipitor Downplays The Significance of TLC.....	28

D.	Pfizer's Illegal Promotion Of Lipitor's Off-Label Use Is Orchestrated At The Highest Levels Of The Company And Is Crucial To The Company's Business Plan .....	28
E.	Pfizer Improperly Utilizes Third-Parties To Promote Its Fraudulent Scheme .....	30
1.	Pfizer Used The National Lipid Education Council To Further Its Scheme To Promote The Off-Label Use Of Lipitor.....	31
2.	Pfizer Used The Emerging Science Of Lipid Management To Further Its Scheme To Promote The Off-Label Use Of Lipitor .....	33
3.	Pfizer Used Independent Consultants To Promote The Off-Label Use Of Lipitor .....	36
VI.	CLASS ACTION ALLEGATIONS .....	37
VII.	COUNTS.....	39

Plaintiffs Southern Illinois Laborers' and Employers Health and Welfare Fund ("Southern Illinois L&E"), NECA-IBEW Welfare Trust Fund ("NECA-IBEW"), and Midwestern Teamsters Health and Welfare Fund ("Midwest Teamsters H&W") (collectively, "Named Plaintiffs"), on behalf of themselves and other third-party payors that paid any portion of the purchase price for Lipitor® (atorvastatin calcium) ("Lipitor") when used under circumstances not specified on its label (collectively, "Plaintiffs") between January 1, 2002 through the present ("Class Period"), by their attorneys, hereby allege, upon knowledge with respect to facts concerning themselves, and as to all other matters, which generally concern facts not in Named Plaintiffs' possession, upon information and belief, as follows:

#### **I. NATURE OF THE ACTION**

1. This is a class action lawsuit asserting claims against defendant Pfizer Inc. ("Pfizer" or the "Company"), on behalf of a proposed nationwide class of health and welfare funds and third-party/payors (collectively "third-party payors") that paid any portion of the purchase price for Pfizer's cholesterol lowering drug Lipitor's off-label use. The complaint, on behalf of a nationwide class, asserts claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO") and for unjust enrichment. Named Plaintiffs also assert claims for fraudulent misrepresentation, negligent misrepresentation, and violations of Illinois' Consumer Fraud and Deceptive Business Practices Act, 815 ILL. COMP. STAT. 505/1 *et seq.*, against Pfizer on behalf of a proposed statewide class of third-party payors located in Illinois that paid any portion of the purchase price for Lipitor's off-label use.

2. The claims against Pfizer arise from the Company's illegal "off-label" promotion of Lipitor for uses that are contrary to the drug's Food and Drug Administration ("FDA") approved uses.

3. For at least the past four years, Pfizer has illegally promoted Lipitor to the public and prescribing physicians by promoting the off-label use of the drug. Pfizer's scheme relied on fraudulently misrepresenting the treatment guidelines established by the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel) ("ATP III") and suggesting its "off-label" marketing of Lipitor actually conformed with ATP III's guidelines. Pfizer has done this through a nationwide campaign that promoted the use of Lipitor in violation of ATP III's guidelines for the initiation of drug therapy. Pfizer also employed purported "independent" third-parties, which were fully funded by Pfizer and/or received other incentives from the Company, to promote Lipitor's off-label use. These third-parties furthered Pfizer's scheme by promoting the off-label use of Lipitor to physicians under the guise of providing physicians educational information concerning the use of statin drugs.

4. Pfizer's scheme has been incredibly successful for the Company. According to the Company's annual report for 2005, Lipitor "is the most widely used treatment for lowering cholesterol and the best-selling pharmaceutical product of any kind in the world reaching over \$12 billion in sales in 2005." However, a significant portion of Lipitor's sales flow from the illegal scheme set forth below.

## **II. PARTIES**

5. Plaintiff Southern Illinois L&E is an employee benefit fund administered pursuant to the terms and provisions of the Agreement and Declaration of Trust creating Southern Illinois L&E and is required to be maintained and administered in accordance with the provisions of the Labor Management Relations Act of 1947, and the Employee Retirement Income Security Act of 1974 (as amended), 29 U.S.C. §§ 1001 *et seq.* The address and place of business of Southern Illinois L&E is 2035 Washington Avenue, Cairo, Illinois 62914. Southern Illinois L&E covers

the cost of health care for eligible participants, including paying for medically necessary uses of drugs. During the Class Period, Southern Illinois L&E paid for Lipitor under circumstances not specified on its FDA-approved label on behalf of persons participating in Southern Illinois L&E's healthcare plan.

6. Plaintiff NECA-IBEW is an employee benefit fund administered pursuant to the terms and provisions of the Agreement and Declaration of Trust creating NECA-IBEW and is required to be maintained and administered in accordance with the provisions of the Labor Management Relations Act of 1947, and the Employee Retirement Income Security Act of 1974 (as amended), 29 U.S.C. §§ 1001 *et seq.* The address and place of business of NECA-IBEW is 2120 Hubbard Drive, Decatur, Illinois 62526. NECA-IBEW covers the cost of health care for eligible participants, including paying for medically necessary uses of drugs. During the Class Period, NECA-IBEW paid for Lipitor under circumstances not specified on its FDA-approved label on behalf of persons participating in NECA-IBEW's healthcare plan.

7. Plaintiff Midwest Teamsters H&W is an employee benefit fund administered pursuant to the terms and provisions of the Agreement and Declaration of Trust creating Midwest Teamsters H&W and is required to be maintained and administered in accordance with the provisions of the Labor Management Relations Act of 1947, and the Employee Retirement Income Security Act of 1974 (as amended), 29 U.S.C. §§ 1001 *et seq.* The address and place of business of Midwest Teamsters H&W is Tedro & Associates, Inc., 2160 Foster Avenue, Wheeling, Illinois 60090. Midwest Teamsters H&W covers the cost of health care for eligible participants, including paying for medically necessary uses of drugs. During the Class Period, Midwest Teamsters H&W paid for Lipitor under circumstances not specified on its FDA-approved label on behalf of persons participating in Midwest Teamsters H&W's healthcare plan.

8. Defendant Pfizer is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. The Company engages in the discovery, development, manufacturing, and marketing of prescription medicines for humans and animals, as well as consumer healthcare products worldwide. Pfizer reported over \$51 billion in revenues for 2005.

### **III. JURISDICTION AND VENUE**

9. This Court has subject matter jurisdiction over this class action pursuant to the Class Action Fairness Act of 2005, Pub.L. 109-2, § 7, 119 Stat. 13. The Class Action Fairness Act, amended 28 U.S.C. § 1332 to add subsection (d) which, as here, confers diversity jurisdiction to this Court as members of the class are citizens from a state which is different than the Defendant's state and the aggregate amount in controversy exceeds five million dollars (\$5,000,000). The Court has personal jurisdiction over the parties because the Named Plaintiffs are located and operating in this state and Pfizer systematically and continuously conducts business in this state, including marketing, advertising, and selling drugs such as Lipitor to residents in this state.

10. The Court also has jurisdiction under 28 U.S.C. § 1331 as Named Plaintiffs' RICO claims arise under 18 U.S.C. § 1962.

11. Venue is proper in this District under 28 U.S.C. § 1391 as the Defendant engaged in substantial conduct relevant to Named Plaintiffs' claims within this District and caused harm to certain Plaintiffs residing within this District.

### **IV. BACKGROUND**

#### **A. Background On Lipitor**

12. Pfizer's single most successful prescription drug is Lipitor. Lipitor is a statin drug that was approved by the FDA for sale to the public on December 18, 1996. Statins reduce

cholesterol levels by blocking the body's production of certain enzymes that are needed to produce cholesterol.

13. In 2001, Pfizer began a national marketing campaign to improperly expand by millions the population for whom Lipitor is prescribed by illegally promoting the off-label and medically unnecessary use of the drug. Since then, it has been cited twice by the FDA for improperly marketing Lipitor by, *inter alia*, downplaying both the harmful side effects of the drug and the importance of diet and exercise in lowering cholesterol. Despite its troubles with the FDA, Pfizer's marketing of Lipitor has been very successful. According to Pfizer's public filings, annual sales of Lipitor have increased from \$5.03 billion in 2000 to \$12.1 billion in 2005, an increase of 140%. Pfizer's campaign has made Lipitor the best selling drug in the United States and the world's first \$12 billion drug. Between 2001 and 2005, Lipitor has generated more than \$46 billion in revenue for Pfizer.

**B. The Food And Drug Administration's Prohibition Of Off-Label Marketing**

14. A manufacturer may distribute a drug only if it is approved by the FDA. *See* 21 U.S.C. § 355(a). In order for the FDA to approve a drug, the manufacturer must show that a drug is "safe for use" for all "conditions prescribed, recommended, or suggested" on a drug's label. 21 U.S.C. § 355(d).

15. A drug is considered misbranded if its label does not contain, *inter alia*, "[s]tatements of all conditions, purposes, or uses for which such drug is intended." 21 C.F.R. § 201.5. *See also* 21 U.S.C. § 331(a) (prohibiting the introduction of misbranded drugs into interstate commerce); 21 U.S.C. § 352(f) (stating that a drug is misbranded if it does not contain "adequate directions for use"). The term "intended" in 21 C.F.R. § 201.5 refers to "the objective intent of the persons legally responsible for labeling drugs [e.g., the manufacturer]." 21 C.F.R.

§ 201.128. Therefore, if a manufacturer intends that a drug be used for a certain purpose, information about that purpose must be on the drug's label and approved as safe by the FDA.

16. Where a manufacturer directly advertises a drug for a particular use, that use is considered an intended use. *See* 21 C.F.R. § 201.128 ("[I]ntent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by . . . [manufacturers] or their representatives."). Therefore, if a drug's manufacturer advertises uses not on its FDA-approved label, the drug is considered misbranded and its distribution in interstate commerce is prohibited. *See* 21 U.S.C. § 331(a).

17. Furthermore, depending on the circumstances, if a manufacturer promotes off-label use indirectly – for example, by sponsoring continuing medical education ("CME") courses that promote off-label use – such off-label use may be considered an intended use if the manufacturer intended that the drug be used for off-label purposes. *See* 21 C.F.R. § 201.128 ("It may be shown by the circumstances that the article is, with the knowledge of . . . [the manufacturer] or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.>").

18. However, the FDA has created certain avenues for manufacturers to communicate off-label information to doctors. A manufacturer may forward off-label information in medical and scientific publications to a physician in response to an unsolicited request. *See* 21 U.S.C. § 360aaa-6.

19. Also, manufacturers may disseminate off-label information to a physician, pharmacy benefit manager, health insurance issuer, group health plan, or Federal or State governmental agency if the manufacturer, *inter alia*, discloses that the use is off-label and provides the disseminated material to the FDA. *See* 21 U.S.C. §§ 360aaa(a)-(c); 360aaa-1.

20. Notwithstanding the FDA's regulation of manufacturers, the FDA does not regulate how doctors prescribe drugs. Physicians may prescribe approved drugs for any purpose that he or she sees fit.

21. The FDA has approved Lipitor for use only in accordance with the ATP III guidelines (described below). Accordingly, any marketing of Lipitor that runs afoul of ATP III is considered off-label marketing and violates FDA regulations.

### **C. The ATP III Guidelines**

#### **1. Summary Of The ATP III Guidelines**

22. The ATP III guidelines, which were developed based upon years of analysis and discussion by NCEP, are incorporated onto Lipitor's Prescribing Information (revised September 2005) (the "Label") and indicate the on-label uses of the drug.

23. ATP III is an evidence-based set of guidelines on cholesterol management that "extensively analyzed the results of recent clinical trials." ATP III at 1-1. ATP III's "major goals were to review the literature objectively and to document and display the scientific evidence for ATP III recommendations." *Id.* The initial guidelines were known as ATP I and ATP II and were adopted in the 1990s. The ATP III guidelines updated the ATP II guidelines in 2001, and were recently updated in 2004.

24. The ATP III report advises physicians on the appropriate stage to initiate drug therapy as opposed to therapeutic lifestyle changes ("TLC"), which include changes to diet and exercise. The ATP III guidelines, which are incorporated into Lipitor's Label, have been adopted by third-party payors as the applicable criteria under which they will pay for Lipitor.

25. ATP III's guidelines set goal low-density lipoprotein ("LDL") levels based on the onset of coronary heart disease ("CHD"), the number of risk factors that may lead to CHD, and a patient's 10-year risk of developing CHD. Risk factors include cigarette smoking, hypertension,

low HDL-C (high-density lipoprotein cholesterol), family history of premature CHD, age, and gender.

26. According to the ATP III guidelines, patients with CHD or CHD risk equivalents have an LDL goal of less than 100 mg/dL; patients with two or more risk factors have an LDL goal of less than 130 mg/dL; and patients with one (or less) risk factors have an LDL goal of less than 160 mg/dL. *See* ATP III at IV-2-4. *See also* Label at 12 table 6.

27. However, the goal LDL levels in the ATP III report are not levels that trigger the use of drug therapy.

28. The ATP III guidelines recommend use of drug therapy to achieve LDL goals based on the following four factors: (1) a patient's LDL level; (2) whether a patient is suffering from CHD; (3) the number of risk factors a patient faces for developing CHD; and (4) a patient's 10-year probability for developing CHD.

29. Based on these factors, the ATP III report segregates patients with high LDL cholesterol into two categories: (1) patients that can be treated with TLC alone; and (2) patients for whom drug therapy may be considered in conjunction with TLC.

30. According to the ATP III report, patients with CHD have a goal LDL of less than 100 mg/dL and TLC should be initiated when the LDL is greater than or equal to 100 mg/dL. For these patients, drug therapy is recommended if their LDL level is equal to or greater than 130 mg/dL and is optional if their LDL is between 100 mg/dL and 129 mg/dL. The 2004 updates recommend drug therapy when the patient's LDL is above 100 mg/dL. The updates also create a group of "very high risk" patients with an LDL goal of 70 mg/dL.

31. Patients with multiple (2 or more) risk factors have an LDL goal of less than 130 mg/dL. For these patients, TLC should be initiated if their LDL level is greater than or equal

to 130 mg/dL. If a patient's 10-year CHD risk is between 10% and 20% drug therapy may be considered if the patient's LDL level is greater than or equal to 130 mg/dL. The 2004 updates provide an optional goal of 100 mg/dL and also provide the option of using drug therapy to reach this goal.

32. Significantly, for a patient with multiple risk factors and a 10-year CHD risk of less than 10%, drug therapy can only be considered if the patient's LDL is greater than or equal to 160 mg/dL, well above their LDL goal of 130 mg/dL. According to NCEP, there are 14.6 million people in this group who do not need drug therapy (those with multiple CHD risk factors and LDL levels between 130 mg/dL and 159 mg/dL). This group is the primary target of Pfizer's scheme.

33. The ATP III guidelines clearly articulate that patients with multiple risk factors and less than a 10% chance of developing CHD are not candidates for drug therapy unless their LDL is greater than or equal to 160 mg/dL:

The LDL-cholesterol goal for multiple risk factors and 10-year risk <10 percent also is <130 mg/dL. However, LDL-lowering drugs are not to be considered unless LDL cholesterol remains  $\geq 160$  mg/dL on TLC. When 10-year risk is <10 percent, cost-effectiveness of drug therapy begins to erode, especially when the LDL-cholesterol level remains in the range of 130 to 159 mg/dL and other risk factors are appropriately controlled. On the other hand, when LDL-cholesterol concentrations  $\geq 160$  mg/dL occur with multiple (2+) risk factors, longterm (>10-year) risk for CHD is relatively high. Thus, drug therapy deserves consideration. Of course, costs and side effects of drugs must also be taken into account when contemplating lifetime drug therapy.

ATP III at VI-6 (emphasis added). The 2004 updates did not make any changes to this group.

34. Finally, patients who are not suffering from CHD and have one or less risk factor have a goal LDL of less than 160 mg/dL. For this group, ATP III recommends TLC if the patient's LDL is greater than or equal to 160 mg/dL and recommends that drug therapy may be

initiated the patient's LDL level is greater than or equal to 190 mg/dL with an option to treat with drugs when LDL is between 160 mg/dL and 189 mg/dL.

35. For all patient groups, ATP III recommends that TLC, including changes in diet and increased exercise, be tried before starting drug therapy.

## **2. The Purpose Behind The ATP III Guidelines**

36. The ATP III guidelines are promulgated on both a risk/benefit and cost/benefit analysis that weighs the health risks and the financial costs of statin therapy with the potential benefits statins provide to patients.

37. The use of statins expose patients to several adverse health risks. Some practitioners have stated that 20% of patients using statins experience some side effects. See John Fauber, *Doubts Raised Over Drugs For Cholesterol*, MILWAUKEE JOURNAL SENTINEL, Mar. 27, 2004.

38. Lipitor's Label itself includes a laundry list of potentially adverse consequences that may result from the drug's use. According to Lipitor's Label, patients using Lipitor face an increased risk of suffering adverse reactions including pain, digestive problems, respiratory problems, rashes, and potentially fatal complications of the liver and skeletal muscle.

39. Moreover, Lipitor should not be used by childbearing women as the drug may injure fetuses: "[LIPITOR] SHOULD BE ADMINISTERED TO WOMEN OF CHILDBEARING AGE ONLY WHEN SUCH PATIENTS ARE HIGHLY UNLIKELY TO CONCEIVE AND HAVE BEEN INFORMED OF THE POTENTIAL HAZARDS." Lipitor Label at 13 (emphasis in original).

40. The health risks of statin use are far from clear. Statin users have reported intense pain that "engulf[ed] every muscle" in the body and pain which continued years after terminating statin therapy. John Fauber, *Doubts Raised Over Drugs For Cholesterol*, MILWAUKEE JOURNAL

SENTINEL, Mar. 27, 2004. Others have linked Lipitor use to cognitive problems such as memory loss. *Id.* A 2003 article by Maryann Napoli states: "Thousands of cases of memory dysfunction have been reported to the FDA's Medwatch program . . . but after two years, the agency still hasn't acted. And most practicing physicians are unaware of the problem. Lipitor is not the only statin linked to this side effect. . . ." Maryann Napoli, *Cholesterol Skeptics and the Bad News About Statin Drugs*, CENTER FOR MEDICAL CONSUMERS, June 2003 (emphasis added).

41. The health risks associated with statin use was one factor used by the ATP III Panel to promulgate the recommended uses of statin drugs. Scott Grundy, M.D., Ph.D., who served as the Chair of NCEP ATP III, states: "[S]tatins, like all drugs, can have side effects, and care must be taken in the use on persons with predisposing conditions. Moreover, it seems unwise to use statins outside current cholesterol-management guidelines." Scott M. Grundy, *The Issue of Statin Safety: Where Do We Stand?*, CIRCULATION, June 14, 2005 (emphasis added). Dr. Grundy cites to the ATP III guidelines in support of his statement.

42. In addition to the health risks, statins also impose monetary costs on society's already strained healthcare system. ATP III's cost/benefit balancing regarding the use of statins is reflected in the following comments:

The widespread use of LDL-lowering drugs, although potentially effective in reducing the burden of CHD in the United States, would be costly. The fundamental rationale for assessment of economic consequences of LDL-lowering drugs is the reality that resources are limited, whereas demand for medical therapies always exceeds available public resources. Consequently, difficult choices often must be made among potentially beneficial interventions. Resources are best allocated according to potential alternative uses. Evidence of efficacy and safety of drug therapy, a requirement for clinical intervention, is insufficient to make recommendations for drug use in a cost-constrained society. This is particularly true when many millions of persons are potential recipients of the therapy. Limited resources should be targeted to where they provide the greatest health benefits. One of the major

objectives of cost-effectiveness analysis is to facilitate patient selection so that incremental benefits are greatest relative to incremental costs. Thus, for LDL-lowering therapy to be widely used in the U.S. population, it must be cost-effective by current standards.

ATP III at II-55. Therefore, the guidelines were carefully constructed to optimize the use of cholesterol lowering drugs.

43. Pfizer simply cast aside ATP III's careful cost/benefit balancing and devised a scheme to market the drug to people for whom the costs and risks did not outweigh the benefits. A Pfizer slide presentation presented to Pfizer marketers titled "Lipitor POA 1 CEC Session" stated, on slide 47, that "LIPITOR [is] not perceived as a cost-effective means of getting patients to goal." The presentation then instructed marketers to: "[d]emonstrate that LIPITOR meets expanding cholesterol management needs while providing great value to customers." (emphasis added).

#### **D. Lipitor's On Label Indications**

44. Lipitor's Label adopts and incorporates the ATP III recommendations for initiating drug therapy for patients with multiple risk factors. Specifically, under the "Indications and Usage" section of the Label, Pfizer states, "Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol only when the response to diet and other nonpharmacological measures has been inadequate." See Lipitor Label at 12.

45. The Label further states, "Before instituting therapy with atorvastatin, an attempt should be made to control hypercholesterolemia with appropriate diet, exercise, and weight reduction in obese patients, and to treat other underlying medical problems."

46. Finally, the Lipitor Label permits the use of the drug in persons with multiple risk factors who have a less than 10% chance of developing CHD within 10-years only if the patient's LDL is greater than or equal to 160 mg/dL.

47. The following chart, which is included in Lipitor's Label (Label at 12), clearly illustrates that Lipitor should be prescribed in accordance with the ATP III guidelines:

**TABLE 6. NCEP Treatment Guidelines: LDL-C Goals and Cutoffs for Therapeutic Lifestyle Changes and Drug Therapy in Different Risk Categories**

Risk Category	LDL-C Goal (mg/dL)	LDL Level at Which to Initiate Therapeutic Lifestyle Changes (mg/dL)	LDL Level at Which to Consider Drug Therapy (mg/dL)
CHD <sup>1</sup> or CHD risk equivalents (10-year risk ≥20%)	100	≥100	≥130 (100-129: drug optional) <sup>2</sup>
2 <sup>+</sup> Risk Factors (10-year risk ≥10%)	130	≥130	10-year risk 10%-20%: ≥130 10-year risk ≥20%: ≥160
0-1 Risk factor <sup>3</sup>	160	≥160	≥190 (160-189: LDL-lowering drug optional)

<sup>1</sup> CHD, coronary heart disease

<sup>2</sup> Some authorities recommend use of LDL-lowering drugs in this category if an LDL-C level of 100 mg/dL cannot be achieved by therapeutic lifestyle changes. Others prefer use of drugs that primarily modify triglycerides and HDL-C, e.g., nicotinic acid or fibrates. Clinical judgement also may call for deferring drug therapy in this subcategory.

<sup>3</sup> Almost all people with 0-1 risk factor have 10-year risk <10%; thus, 10-year risk assessment in people with 0-1 risk factor is not necessary.

48. Since the ATP III guidelines form the basis for Lipitor's prescribing information, promoting Lipitor for patients who do not fall into the ATP III guidelines for drug therapy is illegal, off-label marketing.

49. Despite the language on Lipitor's Label incorporating the ATP III recommendations, as explained in detail below, Pfizer immorally and illegally launched a marketing campaign that minimized and ignored the need for TLC and stated that Lipitor should be prescribed for a group of people for whom TLC is the only recommended treatment. Specifically, Pfizer has misled doctors and patients by illegally promoting Lipitor for use by

patients with multiple risk factors where their LDL is greater than 130 mg/dL regardless of their 10-year risk of developing CHD.

50. By improperly expanding Lipitor's use to patients with LDL levels less than 160 mg/dL who face less than a 10% chance of developing CHD within 10 years, Pfizer has increased its potential market for Lipitor by billions of dollars annually.

51. Thus, Pfizer's scheme, while profitable to the Company, caused Lipitor to be prescribed to persons for whom the drug is not medically necessary. Accordingly, the Company has illegally cost third-party payors billions of dollars as they have unwittingly paid for Lipitor's off-label use.

**E. Pfizer's Scheme Defrauds Medicare And Medicaid**

52. Pfizer's marketing of Lipitor for off-label uses also illegally caused Medicare, Medicaid, and other government programs to pay for off-label uses of Lipitor in violation of applicable payment guidelines.

53. Medicare is a national health insurance program that provides health insurance to people age 65 or older, people entitled to Social Security disability payments for 2 years or more, and people with end-stage renal disease, regardless of income. The program was enacted July 30, 1965, as Title XVIII, Health Insurance for the Aged of the Social Security Act, and became effective on July 1, 1966. Medicare is administered by the federal government. The Medicare Prescription Drug, Improvement, And Modernization Act Of 2003, Pub. L. No. 108-173 (2003), recently added a prescription drug benefit to Medicare.

54. Medicaid is an entitlement program jointly funded by the state and federal government that pays medical costs for the poor and medically needy.

55. Under federal law, the Medicaid program cannot cover the cost of prescription drugs unless the drug is identified as a "covered outpatient drug[.]" 42 U.S.C. § 1396b(i)(10).

The definition of covered outpatient drugs excludes any drug not used for a "medically accepted indication." 42 U.S.C. § 1396r-8(k)(2)-(3) ("[A covered outpatient drug] does not include any such . . . drug or biological used for a medical indication which is not a medically accepted indication"). A "medically accepted indication" in turn is defined as a "use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 301 *et seq.*]" or a use which is "supported by one or more citations included or approved for inclusion in any of the compendia" listed in the statute. *See* 42 U.S.C. § 1396r-8(k)(6). *See also* 42 U.S.C. § 1396r-8(g)(1)(B)(i) (identifying compendia as consisting of: American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information; and the DRUGDEX Information System). A drug's label generally only contains information about uses approved by the FDA. Drugs are only approved for use by the FDA where a manufacturer demonstrates that the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling." 21 U.S.C. § 355(d).

56. Accordingly, Medicaid cannot legally reimburse the cost of off-label drug uses that are not specifically identified in a drug compendium.

57. Neither Lipitor's Label nor the drug compendia identified in the Medicaid statute permit the use of statin drug therapy when a patient's LDL is less than 160 mg/dL when they face less than a 10% chance of developing CHD within 10-years. Accordingly, Lipitor's use in these patients cannot be reimbursed by Medicaid under prevailing Medicaid payment rules.

58. Similarly, Medicare's New Prescription drug benefit program defines covered drugs in the same manner as Medicaid. *See* Pub. L. No. 108-173 Sec. 1860D-2(e) (defining covered drug to include "a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927 k(2) [42 U.S.C. § 1396r-8(k)(2)]

(defining covered outpatient drug to be limited to approved uses or uses described in a compendia))).” Therefore, Medicare cannot legally pay for unnecessary, off-label prescriptions of Lipitor.

59. However, as a consequence of Pfizer’s scheme, Medicare and Medicaid paid billions of dollars to cover the off-label and medically unnecessary use of Lipitor.

**F. Pfizer Defrauds Third-Party Payors**

60. Third-party payors use formularies to determine what drugs to cover for beneficiaries. Formularies are lists of drugs that third-party payors will pay for. The decision to include a drug on a formulary is based on whether a drug is a cost-effective treatment for a particular illness. Generally, formularies create tiers of drugs to incentivize patients to choose certain drugs over more expensive alternatives. For example, patients will generally incur the lowest out of pocket expense for generic drugs or brand drugs that a third-party payor deems particularly cost-effective. However, patients will have to pay a higher out of pocket expense and may have to pay the entire cost of a drug that a third-party payor deems is not a cost-effective treatment.

61. Third-party payors will also place certain drugs on formularies but take additional steps to ensure that the drugs are used in a cost-effective manner. By way of example, some third-party payors require a patient’s physician to call the third-party payor and certify that the patient meets certain clinical criteria before paying for high-risk drugs.

62. Not knowing that Pfizer was engaged in a massive fraudulent scheme to cause the over-prescription of Lipitor, Plaintiffs did not take the necessary steps to ensure the drug was not being over-prescribed.

63. Specifically, Pfizer exploited the fact that third-party payors were unaware of Pfizer’s illegal marketing scheme, did not realize the potential for over-prescription caused by

Pfizer's actions, and therefore did not take precautionary measures reserved for drugs with a danger of being used in medically unnecessary ways.

64. Pfizer's effort to be included in formularies was very successful. Sometime in December 2002, the Company distributed "The Lipitor Healthcare Cluster Playbook" ("Healthcare Playbook") to sales representatives. The Healthcare Playbook, which forbids copying, detailing or distributing, was intended for use by Pfizer's Health Care Cluster, a group of clinical and non-clinical sales persons responsible for increasing the number of Pfizer's institutional customers, such as large employers and managed care organizations. The Healthcare Playbook touts Pfizer's success, stating: "LIPITOR is now on 90% of formularies and is available to 9 of 10 patient lives in the managed care setting. This outstanding formulary penetration and successful messaging has been integral to the impressive sales growth of LIPITOR in 2002. Congratulations!"

## **V. PFIZER'S SCHEME**

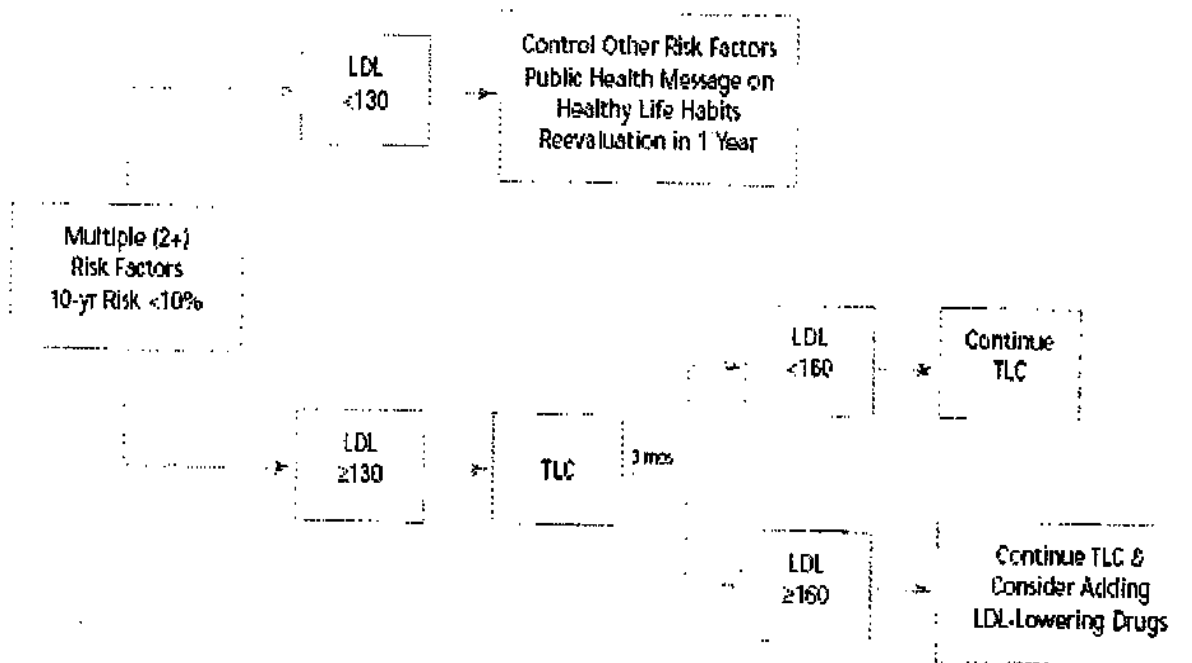
### **A. Pfizer's Scheme Targets A Defined Group Of Persons**

65. Pfizer's scheme focused on expanding the number of patients taking Lipitor beyond what ATP III and the Label recommend. ATP III guidelines recommend that patients with multiple risk factors and less than a 10% risk of developing CHD over the next 10 years may be considered for drug therapy only if their LDL level is 160 ml/dL or higher. For patients with an LDL between 130 ml/dL and 159 ml/dL, the ATP III guidelines recommend only TLC. Nonetheless, Pfizer illegally promotes the drug for use in this patient population.

66. The following chart from the ATP III report illustrates the Panel's recommendations for initiating drug therapy for patients with multiple risk factors but a less than a 10% chance of developing CHD within 10-years:

Figure W2-3. Hyperlipidemia guidelines for the patient with multiple risk factors, 10-year risk <10 percent

The LDL cholesterol goal is <130 mg/dL. Drug therapy can be considered if LDL cholesterol is  $\geq 160$  mg/dL after a trial of TLC.



#### ATP III Report at IV-7.

67. As illustrated in the forgoing chart, the LDL level at which to initiate drug therapy is considerably higher than the LDL goal level of persons with multiple CHD risk factors whose 10-year CHD risk is less than 10%. Pfizer, however, targeted the group of patients with LDL levels between 130 mg/dL and 159 mg/dL with less than a 10% chance of developing CHD within 10-years because there are over 14 million potential Lipitor users in that group.

**B. Pfizer's Illegal Promotion Of Lipitor Targets Pharmacy Benefit Decision Makers, Physicians, And Consumers**

68. Pfizer promoted the off-label use of Lipitor through a nationwide campaign using promotional materials and programs for its core customer segments: pharmacy benefit decision makers, physicians, and consumers.

69. Pfizer's marketing materials include: ATP III training slides for Pfizer employees and external audiences, such as the Physician Speaker's Bureau; computer software programs, internet programs; health fair programs; "leave behind" materials; and visual aids. For all of these target populations, the same false message, contrary to Lipitor's FDA-approved label and ATP III's recommendations was created: ATP III recommends drug therapy for all patients with multiple risk factors regardless of their 10-year risk of CHD if their LDL levels are greater than their LDL "goal" of 130 mg/dL.

70. Pfizer's marketing scheme was carried out despite the Company's knowledge that the ATP III guidelines state that the LDL "goal" is not the LDL level for initiating drug therapy and that the guidelines do not recommend drug therapy for patients with a less than 10% risk of developing CHD within 10 years unless their LDL level is greater than or equal to 160 mg/dL.

71. Pfizer ignored the guidelines and launched a marketing campaign that sought to treat any person not at "goal" with Lipitor.

**1. Pfizer Illegally Promotes The Off-Label Use Of Lipitor To Pharmacy Benefit Decision Makers**

72. Pfizer illegally promotes Lipitor to Pharmacy Benefit Decision Makers ("PBDMs"), persons who help third-party payors design their pharmacy benefit plans. PBDMs often assist third-party payors develop formularies, which entails making choices about which drugs to cover and how much third-party payors will reimburse for certain drugs.

73. In presentations to PBDMs, Pfizer illegally promoted off-label use of Lipitor by stating that all patients with multiple risk factors of CHD should be treated with Lipitor if they are unable to reach their cholesterol goal. In reality, ATP III, incorporated by reference on the Label, only recommends that for persons with multiple risk factors of CHD but less than a 10% chance of developing CHD within 10-years, Lipitor should only be prescribed if the patient's LDL is greater than or equal to 160 mg/dL. This is well above their goal of 130 mg/dL and thus Pfizer seeks to have Lipitor prescribed for millions of persons with LDL between 130 mg/dL and 159 mg/dL, even though drug therapy for these patients is unnecessary, expensive and exposes patients to medically unnecessary risks.

74. Specifically, one of Pfizer's programs aimed at PBDMs, "Cholesterol Management in the Work Place: Information for Benefit Decision Makers," stresses "the cost of lost productivity due to uncontrolled cholesterol" in the workplace. As part of the marketing program, Pfizer representatives use a compact disc containing a slide presentation and also a "leave behind" brochure. The compact disc includes a series of slides grouped into the following categories: (1) "The Prevalence and Cost of High Cholesterol;" (2) "The Treatment Gap;" (3) "Therapeutic Options;" and (4) "Workplace Initiatives."

75. One slide on the compact disc in the "Therapeutic Options" section entitled "When to consider drug therapy in the management of high cholesterol" fraudulently mischaracterizes the ATP III guidelines. At the bottom of the slide, in large font for emphasis, are instructions for the Pfizer marketing employees who give the presentation that states: "For individuals with <20% risk, drug therapy may be considered after lifestyle changes alone have failed to achieve LDL goal." This recommendation is contradicted by the ATP III guidelines, which do not recommend drug treatment for those patients with multiple risk factors who face

less than a 10% chance of developing CHD within 10 years unless their LDL is equal to or greater than 160 mg/dl..

76. Pfizer's fraudulent statements to PBDMs were incorporated into more than one presentation. As part of a separate presentation to PBDMs entitled "Lipid lowering and prevention of coronary heart disease: A managed care perspective," Pfizer included similar fraudulent statements in a leave-behind brochure. The brochure contains a chart showing LDL goals accompanied by the following statement: "Lowering lipid levels can help prevent CHD." The brochure conveys the misleading impression that Lipitor should be used by all patients who are unable to reach their cholesterol goal when in reality the ATP III guidelines recommend that a substantial number of people only begin Lipitor treatment when well (30 mg/dl. or more LDL points) above goal.

77. Pfizer also illegally promoted the off-label use of Lipitor through a slide presentation entitled "Lipid Lowering Slide Kit" that was included on two compact discs as part of Pfizer's "Lipid Lowering and Prevention of Coronary Heart Disease: A Managed Care Perspective" marketing program. The first CD contains a slide entitled "The first step in reducing LDL-C: Therapeutic Life Changes (TLC)." The slide states that if LDL goal is not achieved through TLC, drug therapy should be considered." In this statement, Pfizer is improperly promoting an off-label use of Lipitor as the ATP III guidelines recommend that many patients consider drug therapy when their LDL level is well above their ultimate goal.

78. Unaware of Pfizer's scheme PBDMs included Lipitor on their drug formularies, thereby increasing the market for Lipitor.

**2. Pfizer Illegally Induces Physicians To Prescribe Lipitor For Off-Label Uses**

79. Pfizer's promotion of Lipitor's off-label use was also targeted at physicians. Pfizer used outreach programs, speaker events, sales calls, and computer software to mislead doctors about the FDA-approved uses of Lipitor. For example, Pfizer's Lipitor 2002 US Operating Plan ("Operating Plan") laid out the Company's illegal scheme. According to that document, Pfizer's primary concern when communicating to doctors about Lipitor was to "Emphasize New LIPITOR 'Get to Goal' Messages."

80. It is clear that Pfizer's "Get to Goal Message" entailed advertising Lipitor for use in patients above goal, but for whom ATP III did not recommend drug treatment. Therefore, when Pfizer communicated information about Lipitor to physicians, Pfizer fraudulently told them that ATP III recommended that they should prescribe Lipitor to all patients who could not reach their LDL goal.

81. As part of their marketing campaign, Pfizer prepared a standard slide presentation that fraudulently mischaracterized the ATP III guidelines. These slides were designed and approved by Pfizer's Corporate Lipitor Disease Management Team and used by Pfizer for different purposes including: (1) to train Pfizer's clinical and non-clinical personnel and paid physician consultants; (2) to "educate" Pfizer's customers; and (3) to serve as the basis for Pfizer's presentation given to doctors encouraging them to prescribe Lipitor. The slide presentation enables Pfizer to uniformly promote the off-label use of Lipitor on a massive scale.

82. One of the misleading slide presentations is entitled "The Lipid Slide Library Volume 2: National Cholesterol Educational Program Adult Treatment Panel III Guidelines." The slide presentation is accompanied by speaker notes. The speaker notes to slide 1 state: "This program highlights the new NCEP ATP III guidelines for your clinical practice, as well as

information on lipid-lowering therapy with atorvastatin calcium [Lipitor]." However, the slides are intended to promote the off-label use of Lipitor by falsely stating that ATP III recommends that all patients who were not able to reach LDL goal with TLC should begin Lipitor. Specifically, the commentary for slide 14 falsely states: "[L]ipid-lowering drug therapy should be considered for patients not at LDL goal after 3 months of therapeutic lifestyle changes." The slide presentation never states that for certain patients, Lipitor therapy should not be initiated unless the patient's LDL is greater than or equal to 160 mg/dL, well above their goal of 130 mg/dL.

83. This slide presentation was repeated to doctors around the country numerous times. For example, Pfizer's Local Marketing Team in Atlanta created the Cardiovascular Leadership Council ("CLC") in 2002 to further the reach of Pfizer's illegal marketing campaign. The CLC was designed to influence "thought leaders and targeted physicians" with Pfizer's misleading message. As part of the program, Pfizer sponsored promotional dinners and CME courses for both cardiologists and primary care physicians. The program was intended to increase market share of Lipitor "by educating physicians in the marketplace about the importance of treating to goal." As part of "educating" physicians, the CLC provided speakers to their events with the misleading slide presentation promoting Lipitor's off-label use.

84. Additionally, Pfizer also illegally promoted the off-label use of Lipitor to rural physicians through Pfizer's program entitled "Pfizer Facilitating the Advancement of Rural Medicine" or "PFARM." As part of PFARM, Pfizer sent speakers to give misleading presentations to rural doctors about the use of drug therapy to control LDL. PFARM's purported objective was to "provide rural practitioners with solutions to managing patients with high-risk and potentially costly conditions (hypertension and hypercholesterolemia)." Again, Pfizer gave

these speakers slides that deceptively gave the impression that all patients should be treated with Lipitor if they are unable to get to their LDL goal. In reality, ATP III only recommends that a fraction of these patients consider using Lipitor if they are not at goal; for patients with multiple risk factors of CHD and less than a 10% chance of developing CHD within 10 years, ATP III does not recommend Lipitor treatment unless their LDL is greater than or equal to 160 mg/dL.

85. For example, slide 18 of the PFARM presentation presents ATP III's LDL goals without stating that ATP III sometimes recommends that physicians initiate Lipitor treatment at levels higher than goal. Both "moderate risk" patients (patients with multiple risk factors and less than a 10% chance of developing CHD within 10-years) and "moderately high risk" patients (patients with multiple risk factors and a 10% to 20% chance of developing CHD within 10-years) were confusingly grouped together as having an LDL goal of 130 mg/dL. ATP III guidelines, however, clearly recommend that moderate risk patients consider drug therapy only if their LDL cholesterol is greater than or equal to 160 mg/dL.

86. In its first national training meeting of 2002 for Pfizer's pharmaceutical sales representatives, entitled POA 1 (Plan of Action), Pfizer introduced a program called "POA Strategic Selling Guide Featuring Action Selling." It encourages Pfizer marketers to adopt three strategies: (1) encourage physicians to identify new patients for treatment; (2) illustrate safety and efficacy; and (3) dominate share of voice with detail frequency and strategic sample distribution. At POA 1, another message Pfizer wanted its marketers to convey to doctors was that they have the "[p]ower to help the majority of patients reach their goal."

87. Pfizer also used computer software to perpetuate its scheme. Specifically, a software program entitled "Lipid Goal Manager" was distributed in the Healthcare Playbook (*see supra* at ¶64). The software was intended to be used by marketers to help physicians "integrat[e]

NCEP ATP III guidelines into routine practices.” The software enabled doctors to input certain variables about a patient (age, sex, and LDL cholesterol level) and then analyze whether the patient was at their ATP III goal. However, as illustrated below, the software illegally promoted the off-label use of Lipitor.

88. For example, if the following patient information is entered into the software program - 43 year-old female with LDL-C of 135 mg/dL and three risk factors - the following report is generated:

RISK ASSESSMENT AND LDL GOAL

NCEP Risk Category: 2 or more risk factors (10-year risk <20%)

NCEP LDL-C level: <130 mg/dL

Patient's LDL-C level: 135 mg/dL

Patient's 10-year risk: 4 percent

TO MEET NCEP GOAL LDL-C, LEVELS SHOULD BE  
 LOWERED BY 6 mg/dL OR MORE (4.44 percent)

89. Similarly, if the following patient information is entered into the database - 43 year-old male with LDL-C of 131 mg/dL and two risk factors - the following report is generated:

RISK ASSESSMENT AND LDL GOAL

NCEP Risk Category: 2 or more risk factors (10-year risk <20%)

NCEP LDL-C level: <130 mg/dL

Patient's LDL-C level: 131 mg/dL

Patient's 10-year risk: 8 percent

TO MEET NCEP GOAL LDL-C, LEVELS SHOULD BE  
 LOWERED BY 2 mg/dL OR MORE (1.53 percent)

90. In both cases, Pfizer programmed the software to generate a deceptive letter that the physician could send to his patients. For the two patients above, the software generated a letter that stated: “[A] low fat diet, proper exercise, and medication will help lower your cholesterol levels, especially your LDL-cholesterol (had cholesterol). . . .” (emphasis added).

91. However, based on ATP III guidelines, these patients should not be considered for drug therapy because both patients’ risk of developing CHD within 10 years was less than 10% and their LDL was less than 160 mg/dL. Therefore, creating software that falsely stated that medication will help lower their LDL, when ATP III only recommends TLC for these patients, was another facet of Pfizer’s scheme to increase the patient population of Lipitor through the use of deception.

92. Furthermore, the software also generates a report that doctors can give to patients entitled: “What is your cholesterol goal?” It shows three risk categories and three goals for “bad” LDL. The second category is “two or more risk factors and a 10-year coronary heart disease risk of <20%” and the LDL goal for the category is “below 130 [mg/dL].” The report, however, neglects to state that a significant percentage of these patients, those with less than a 10% chance of developing CHD, should not begin drug therapy unless their LDL cholesterol is greater than or equal to 160 mg/dL.

93. Pfizer also used its website to illegally promote the off-label use of Lipitor to physicians. Specifically, the Company stated that ATP III updated the existing guidelines and reduced LDL goal from 130 mg/dL to an optional goal of 100 mg/dL for patients with two risk factors of CHD. However, that statement is false. The ATP III 2004 updates only recommended an optional goal of 100 mg/dL for patients with multiple risk factors and a 10% to 20% chance of developing CHD in the next 10 years. For patients with two or more risk factors of CHD with

less than a 10% chance of developing CHD in the next 10 years, the 2004 ATP III updates left the LDL goal of 130 mg/dL unchanged.

### **3. Pfizer Illegally Promotes Lipitor's Off-Label Use To Consumers**

94. To target Hispanic consumers directly with the Company's illegal marketing scheme, Pfizer implemented a number of direct to consumer ("DTC") marketing programs. One program, the Sana La Rana program, targeted "low health literacy" Spanish speaking populations. It utilized print, radio, and television advertising and also had a website. The website sought to promote the off-label use of Lipitor by stating that people with multiple risk factors of CHD have an LDL goal of 130 mg/dL while failing to mention that those with a less than a 10% risk of CHD should not start Lipitor unless their LDL is greater than or equal to 160 mg/dL.

95. The Sana La Rana project had a large impact on consumers. The campaign ran from June 2003 to December 2003. In that time, Pfizer distributed 400,000 patient education brochures and hosted 282 community charlas (chats) that reached 4,300 people in Houston and Miami. Its website received 13,000 hits and it received 5,300 phone calls.

96. Another marketing campaign directed at consumers, the "Boston Heart Party," which describes itself as "Boston's leading cardiovascular disease awareness campaign for women," similarly misrepresents the ATP III guidelines. An email message from Valerie Sullivan, Pfizer's Director of Marketing for the Boston Local Market Team, stated: "[T]he educational piece of [the Boston Heart Party] would highlight the importance of treating aggressively to goal, especially in light of the new ATP III goals." Like much of Pfizer's marketing campaign, it did not inform consumers that for a large number of patients, ATP III does not recommend drug therapy unless the person is at least 30 mg/dL points above their LDL goal.

**C. Pfizer's Scheme To Promote The Off-Label Use Of Lipitor Downplays The Significance Of TLC**

97. In order to illegally increase Lipitor's off-label use, Pfizer also downplayed the importance of TLC in controlling LDL levels. Specifically, consumers who register at Lipitor.com are emailed a message stating "Don't worry, a high cholesterol number may not be your fault. But it's probably time for some extra help." The message also contains a link stating: "Get up to \$10 off a Lipitor prescription. It's a great way to get started." Pfizer's email deceptively omits that under ATP III guidelines, diet and exercise should be tried before starting Lipitor.

98. Pfizer also sought to downplay the importance of TLC in its DTC advertising. Specifically, on page 55 of the Operating Plan (dealing with DTC advertising), Pfizer outlines its marketing strategies which seek to saturate consumers with messages such as "High cholesterol is not your fault and your doctor can help you" and "Lipitor is the most effective treatment." These statements are misleading because they downplay the importance that TLC can make in reducing cholesterol and also run afoul of the ATP III's guidelines that recommend initially using TLC to reach LDL goals.

**D. Pfizer's Illegal Promotion Of Lipitor's Off-Label Use Is Orchestrated At The Highest Levels Of The Company And Is Crucial To The Company's Business Plan**

99. Pfizer's illegal scheme to promote the off-label use of Lipitor was orchestrated at the highest levels of the Company and was critical to its business model.

100. In communications to investors, Pfizer touted the potential "market" for Lipitor and the prospects for Lipitor's success. However, Pfizer's touting of Lipitor's potential growth failed to inform investors that this explosive growth could only be achieved if Lipitor was prescribed for off-label, non-compendium use for millions who did not need it and for whom

ATP III only recommended TLC. In its representations to investors, Pfizer suggested that all persons not at their LDL goal could benefit from Lipitor. According ATP III guidelines, this simply was not true.

101. Specifically, Pfizer's Second-Quarter 2004 Performance Report, which was filed with the SEC on Form 8-K on July 21, 2004, blatantly promotes Lipitor's off-label use as a business opportunity for Pfizer. In the performance report, Karen Katen – currently Vice Chairman of Pfizer, President of Pfizer's Human Health Division, and a member of the Company's Executive Committee – states: “[f]resh evidence on statins, and the new U.S. guidelines it has driven, portend more growth potential for Lipitor. Landmark studies such as ASCOT-LLA, CARDS, PROVE-IT, REVERSAL, and Alliance have demonstrated the dramatic health benefits of ever-lower cholesterol, as effected by Lipitor, benefits such as reduced strokes, heart attacks, and the need for invasive procedures. The medical community's growing recognition of this value means in the U.S. alone, 18.5 million new patients could benefit from lipid-lowering therapy, elevating the number of Americans Lipitor could help to about 79 million, or 40 percent of all adults. This new evidence on Lipitor underscores the opportunities for even our major products to help substantially more patients.” (emphasis added).

102. Pfizer never cites a source for its estimate that 79 million people could benefit from Lipitor. Moreover, Pfizer's estimated 79 million potential Lipitor users is wholly inconsistent with NCEP estimates. As stated above, NCEP has estimated that approximately 37 million people are eligible for statin drug therapy under ATP III. Even considering that the 2004 updates to ATP III, which have not yet been incorporated in Lipitor's FDA-approved label, expanded the potential patient population for Lipitor, Pfizer's statement that 79 million persons could benefit from Lipitor is blatantly wrong. See John Fauber, *Doubts Raised Over Drugs For*

*Cholesterol*, MILWAUKEE JOURNAL SENTINEL, Mar. 27, 2004 (statins are recommended for 36 million Americans). *See also* Bennett M. Paone, Managing dyslipidemias: update on guidelines and pharmacotherapy, available at [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=retrieve&db=pubmed&dopt=Abstract&list\\_uids=12296547&query\\_hl=2&itool=pubmed\\_docsu](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=retrieve&db=pubmed&dopt=Abstract&list_uids=12296547&query_hl=2&itool=pubmed_docsu) m (accessed Mar. 19, 2006) ("Based on ATP III, 65 million Americans need therapeutic lifestyle changes, 36.5 million of whom require drug therapy."). Despite the fact that only 36.5 million Americans are eligible for statin therapy, Pfizer constructed a massive fraudulent scheme to target 79 million Americans (or 40% of all adults in the United States) to take Lipitor, even though for many of those people Lipitor was a dangerous and unnecessary drug.

**E. Pfizer Improperly Utilizes Third-Parties To Promote Its Fraudulent Scheme**

103. Pfizer paid outside marketing/sales firms, physician consultants, and other consultants who were not employees of Pfizer to fraudulently promote the off-label use of Lipitor. Pfizer also funded third-party entities -- including Emerging Science in Lipid Management ("ESLM") and the National Lipid Education Council ("NLEC") (NLEC changed its name in 2006 to the Committee on Cardiovascular and Metabolic Disease) -- that offered CME courses to doctors and published articles promoting Lipitor's off-label use. ESLM and NLEC both purport to educate physicians about the treatment of high cholesterol. However, both organizations are fully funded by Pfizer and play an important role in the illegal off-label marketing of Lipitor. Pfizer's use and coordination of third-party entities to promote its fraudulent scheme is manifested in its Operating Plan. Page 32 of the Operating Plan is titled "Medical Education Platform Supports the New Positioning." In that section, Pfizer states that it plans to use ESLM and NLEC in its scheme to market Lipitor. As further detailed below, both of these entities, fully funded by Pfizer, deceptively promote off-label use of Lipitor.

**1. Pfizer Used The National Lipid Education Council To Further Its Scheme To Promote The Off-Label Use Of Lipitor**

104. Pfizer is the sole source of funding for NLEC. Pfizer channels money to the organization through an unrestricted educational grant to Thomson Professional Postgraduate Services ("PPS"), a division of Thomson Corporation's healthcare group. PPS "develops medical educational activities designed to meet the needs of practicing physicians. PPS, working with medical leaders, designs and implements effective programs to meet specific educational objectives."

105. According to its mission statement, NLEC began in 1996 as the Lipid Management in Clinical Practice program. Its purported goal is "focused on educating physicians and other healthcare professionals about the rationale for aggressive cholesterol-lowering therapy, specifically to achieve LDL-C targets, in order to prevent or manage adverse cardiovascular events." Furthermore, NLEC claims: "Through multifaceted educational activities — including national and regional symposia as well as a variety of print, audio, and visual media — the NLEC strives to reach healthcare professionals nationwide to effect better health outcomes for patients." In reality, NLEC repeatedly conflated on and off-label uses of Lipitor in an attempt to confuse doctors and increase the number of Lipitor users.

106. CME courses provided by NLEC repeatedly distorted the line between on and off-label use of Lipitor. These CME courses purportedly provide educational material to practicing physicians and are often presented at high-end restaurants, through newsletters, and the internet. One often used technique is to present case studies to physicians of patients who were successfully treated with Lipitor. NLEC's CMEs contain an overall disclaimer stating that "discussions are present of off-label, non-FDA approved uses of certain therapies." Furthermore, in the introduction to online "Virtual Case Studies," the NLEC website states:

“[S]ome treatment[s] outlined in these sections in these cases may not adhere to National Cholesterol Educational Treatment Panel III (ATP III) guidelines.” However, it is wholly unclear from the CME materials what is an approved use and what is not an approved use of the drug, and participants in these programs are not informed which are and which are not approved uses.

107. For example, a CME case study on NLEC’s website promotes the use of a statin in patients with LDL below 160 mg/dL, multiple risk factors, and a 10-year CHD risk of less than 10%. Significantly, at no point does NLEC mention that ATP III guidelines do not recommend treatment for this patient. In fact, the patient in the case study is alternately described as “moderately high risk,” “relatively high risk,” and at “high risk.” According to ATP III guidelines, however, this patient would only need drug therapy if his LDL was greater than or equal to 160 mg/dL. This case is also deceptive because it states ATP III goals without stating cholesterol levels when physicians may consider initiating drug therapy.

108. Pfizer influences NLEC’s operations by retaining NLEC’s leaders as consultants and/or providing research/grant monies to NLEC’s directors. Specifically, Dr. Antonio Gotto, NLEC’s chairman, has been retained by Pfizer as a consultant. Additionally, virtually every member of NLEC’s Steering Committee has served as a Pfizer consultant and/or has received funding from Pfizer. The following members of NLEC’s steering committee also have financial ties to Pfizer: Dr. Peter Ganz (Pfizer consultant); Dr. Steven Haffner (Pfizer consultant and member of Pfizer’s speaker bureau); Dr. Ronald Krauss (Pfizer consultant, member of Pfizer’s speaker bureau, and Pfizer grantee); Dr. John LaRosa (advisor/consultant to Pfizer); Dr. Peter Libby (Pfizer consultant, recipient of grants and research support from Pfizer, and chairman of the steering committee for the Treating to New Targets Study, a Pfizer/Parke-Davis study that

focused on the benefits of atorvastatin in patients with CHD); and Dr. Thomas Pearson (Pfizer consultant and member of the data safety and monitoring board of the PROVE-IT Trial (*see supra*, at ¶101)).

109. Pfizer's ties to Thomson Corp. ("Thomson") extend well beyond its relationship with PPS. Thomson relies on Pfizer for purchasing several products from the company.

110. One such product, Ilectra, is touted by Thomson as being used by Pfizer to unify the Company's "enterprise-wide learning programs." Thomson also touts Pfizer's use of its "MDC" program, which provides IP management services on Thomson Scientific's website.

111. Pfizer also partnered with Thomson Prometric (a division of Thomson), which promotes itself as the global leader in technology-enabled testing and assessment services. A March 30, 2004, press release from Thomson Prometric states: "Thomson Prometric and Pfizer, Inc. have collaborated since 2000. Pfizer discovers, develops, manufactures and markets leading prescription medicines for humans and animals, including some of the world's best-known consumer brands. In 2003, they chose to continue their agreement with Thomson Prometric to take advantage of Thomson Prometric psychometric services."

112. Accordingly, Pfizer and Thomson are associated on several levels beyond Pfizer's reliance on PPS to help it fund NLEC.

## **2. Pfizer Used The Emerging Science Of Lipid Management To Further Its Scheme To Promote The Off-Label Use Of Lipitor**

113. ESLM was mentioned in Pfizer's Operating Plan as a key component to help the Company boost Lipitor's sales. According to ESLM's website, the organization is funded by an unrestricted grant from Pfizer. Moreover, ESLM shares directors with NLEC-- Dr. Gotto (NLEC chairman) and Dr. Libby (NLEC steering committee member) both serve as national faculty co-chairs for ESLM. *See supra*, at ¶108.

114. ESLM's website states: "Launched in the spring of 2001, the Emerging Science of Lipid Management (ESLM) initiative is a strategy for educating physicians across the country about fundamental changes in the scientific and clinical understanding of atherosclerosis and heart disease."

115. Under the Learning Objectives section of ESLM's website the organization states:

The purpose of the Emerging Science of Lipid Management CME initiative is to increase recognition of dyslipidemias, highlight the importance of cardiovascular risk assessment, and foster appropriate early and aggressive treatment and follow-up of lipid abnormalities.

At the conclusion of an ESLM educational activity, the participant should be able to:

- Identify appropriate candidates for aggressive lipid management
- Recognize the benefits of multifactorial lipid therapy in patients, including underserved populations, across the spectrum of cardiovascular disease risk
- Understand the cardiovascular consequences of metabolic dysfunction, including insulin-resistance syndromes, obesity, and diabetes
- Adopt effective strategies for managing dyslipidemia [(abnormal lipid levels)] in everyday clinical practice

116. ESLM's website also notes: "ESLM will directly reach thousands of cardiologists, cardiology fellows, and other physicians through a series of innovative CME-accredited educational activities. In addition, 18,000 cardiologists and 60,000 internal medicine physicians will receive the quarterly *Lipid Letter*, a 12 page newsletter that disseminates the latest findings on managing dyslipidemia." The *Lipid Letter* is co-chaired by Dr. Gotto and Dr. Libby.

117. However, ESLM uses "educational programs" to promote Lipitor's off-label use. In the September 2005 volume of the *Lipid Letter* Dr. Gotto and Dr. Libby wrote an article titled

"Statin Safety: Weighing the Evidence," which stated, contrary to ATP III guidelines, that "reducing serum LDL-L from any baseline level lowered risk further in high-risk patients." (emphasis in original).

118. In 2004, an invitation was mailed to physicians inviting participation in ESLM's national program providing free CME credit entitled "New Paradigms in Cardiovascular Risk Reduction: A CME Teleconference." ESLM's invitation stated: "At the conclusion of this activity, participants should be able to apply NCEP guidelines and other data to management of patients who have, or who are at risk of coronary heart disease." However, during the presentation, participants are given little guidance of where discussion of NCEP guidelines end and where discussion of off-label use of the drug begin. A carefully worded disclaimer states: "Off-Label Discussion: In the event that a speaker discusses a product that is either not approved or the product is investigational, the speaker will disclose this information to the audience at the time of the presentation." However, it is important to note that this disclaimer does not address disclosures concerning Lipitor's off-label uses.

119. ESLM also provided paid consultants from Pfizer a platform to promote Lipitor's off-label use. For example, in a CME titled "A 65-Year-Old African American Man with Low HDL-C," Dr. Matthew Sorrentino, who received funding from Pfizer and has given lectures sponsored by Pfizer, presents a case study where a 65-year old African American male with known CHD and an LDL of 87 mg/dL was given statin therapy for three months. The CME's first key point states, "Therapeutic lifestyle changes should be the initial approach to the treatment of dyslipidemia. In patients for whom this approach is not adequate, statin therapy can help patients meet their target LDL-C level, and fibrate or niacin therapy may be effective in raising low HDL-C levels." (emphasis added). This CME blatantly promotes the off-label

use of Lipitor. First, according to the Label, this patient should not have received statin therapy unless his LDL was greater than or equal to 100 mg/dL. Second, contrary to the CME's key point, according to ATP III guidelines, statin therapy should be administered to patients who are not at their LDL goal after initiating TLC but only if their LDL remains above the number at which ATP III recommends drug treatment.

120. ESLM also provides Pfizer and its paid consultants an outlet to undermine the health concerns expressed over statin use. *See supra*, ¶¶36-41. For example, in the "Patient Education" section of ESLM's website, the organization posted a paper titled "What You Need to Know About . . . Statins and Other Medications For Preventing a Heart Attack." The paper, prepared by Dr. Dennis DeSilvey and funded by Pfizer, downplays the risks associated with statin use. Specifically, in responding to the question "[a]re statins safe?" Dr. DeSilvey writes, "The risk of side effects with statins is very low – only about 1 to 2 chances in 100. Serious side effects are even less common, occurring in about 1 in 1000 patients." The paper also states:

If you choose not to take cholesterol-regulating medication, there's a greater chance that your cholesterol levels can damage your blood vessels, which will increase your risk of having a heart attack or stroke. Keep in mind that your chances of developing heart disease are much greater than your risk of having a bad side effect from taking a statin. The evidence from scientific studies clearly shows that the potential benefits of taking a statin far outweigh the potential risks.

121. Although not disclosed in the preceding paper, the June edition of the *Lipid Letter* states, "Dr. DeSilvey reports that he is on the speakers' bureau for Pfizer Inc."

### **3. Pfizer Used Independent Consultants To Promote The Off-Label Use Of Lipitor**

122. In addition to using NLEC and ESLM to promote Lipitor's off-label use, Pfizer also used paid independent consultants to illegally expand the off-label uses of the drug.

123. A CME titled "Statins May Reduce Cardiovascular Risk in Type 2 Diabetes," released on August 23, 2004, promoted off-label use of Lipitor. As part of the CME, Dr. Helen

M. Colhoun stated that "Atorvastatin 10 mg daily is safe and efficacious in reducing the risk of first cardiovascular disease events, including stroke, in patients with type 2 diabetes without high LDL-cholesterol . . . No justification is available for having a particular threshold level of LDL [low-density lipoprotein]-cholesterol as the sole arbiter of which patients with type 2 diabetes should receive statins." Dr. Colhoun's comments were based on the Collaborative Atorvastatin Diabetes Study ("CARDS") published in the Aug. 21 issue of *The Lancet*. CARDS was funded by, *inter alia*, Pfizer UK and Pfizer Inc. Moreover, according to *The Lancet*, Dr. Colhoun served as a consultant to Pfizer and received travel expenses and payments for speaking at meetings from the Company.

124. Pfizer employed a multifaceted and uniform scheme to misrepresent the ATP III guidelines in order to expand the number of persons using Lipitor. This scheme was carried out without any regard for the safety of people using Lipitor. Pfizer's scheme – which made Lipitor the world's first \$12 billion a year drug – exploited the willingness of third-party payors to pay for on-label uses of Lipitor to promote its off-label sales.

## **VI. CLASS ACTION ALLEGATIONS**

125. Named Plaintiffs bring this action as a class action pursuant to Fed. R. Civ. P. 23(a), (b)(2), and (b)(3) on behalf of a nationwide class of third-party payors that paid any part of Lipitor's purchase price for its off-label use ("Nationwide Class"). Named Plaintiffs seek class certification under Fed. R. Civ. P. 23(b)(2) as to declaratory and equitable relief sought herein, and under Fed. R. Civ. P. 23(b)(3) as to the damages sought herein. The Nationwide Class asserts claims under RICO and unjust enrichment.

126. Named Plaintiffs also bring this action on behalf of a sub-class of third-party payors located in Illinois that paid any part of Lipitor's purchase price for its off-label use ("Statewide Class"). The Statewide Class asserts claims for fraudulent misrepresentation,

negligent misrepresentation, and under Illinois' Consumer Fraud and Deceptive Business Practices Act, 815 ILL. COMP. STAT. 505/1 *et seq.*

127. The Nationwide Class and the Statewide Class are collectively referred to herein as the "Class."

128. Upon information and belief, thousands of third-party payors were induced to pay for Lipitor's off-label use through Pfizer's scheme which illegally promoted the off-label use of the drug. The members of the Class are so numerous and dispersed throughout the United States and the State of Illinois that joinder of all members is impracticable. The Class members can be identified by, *inter alia*, records maintained by Pfizer, drugstores, and PBDMs.

129. Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting solely individual members of the Class. Among the questions of law and fact common to the Class are:

- (a) Whether Pfizer engaged in a scheme to illegally promote the off-label use of Lipitor;
- (b) Whether Pfizer's scheme to promote the off-label use of Lipitor was carried out intentionally with direct knowledge, or at least recklessly by the Company; and
- (c) Whether the members of the Class have sustained damages and, if so, what the appropriate measure of damages should be.

130. The Named Plaintiffs' claims against Pfizer are typical of the claims of the members of the Class as both sustained damages arising out of the Company's wrongful conduct as detailed herein. Specifically, Named Plaintiffs' claims and the Class' claims arise from the Defendant's scheme to illegally promote the off-label uses of Lipitor during the Class Period.

131. The Named Plaintiffs will fairly and adequately protect the interests of the Class and have retained counsel competent and experienced in class action lawsuits. The Named

Plaintiffs have no interests antagonistic to or in conflict with those of the Class and should be named as representatives for the Class.

132. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since joinder of all members of the Class is impracticable. Furthermore, because the damages suffered by individual members of the Class may in some instances be relatively small, the expense and burden of individual litigation make it impossible for such class members individually to redress the wrongs done to them. Also, the adjudication of this controversy through a class action will avoid the possibility of inconsistent and possibly conflicting adjudications of the claims asserted herein. There will be no difficulty in the management of this action as a class action.

## VII. COUNTS

### Count I

#### **Violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961, *et seq.***

133. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

134. The Named Plaintiffs, the members of the Class, Pfizer, physician consultants employed by Pfizer to promote the off-label use of Lipitor, Thomson, PPS, ESLM, and NLEC are each "persons" as that term is defined in 18 U.S.C. § 1961(3).

135. During the relevant time period described herein, Pfizer conducted the affairs of an association-in-fact enterprise identified herein. The conduct of the association-in-fact affected interstate commerce through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

136. For the purposes of this claim, the RICO enterprise is an association-in-fact consisting of: (1) Pfizer; (2) physician consultants employed by Pfizer to promote the off-label

use of Lipitor; (3) entities fully funded by Pfizer, including ESLM and NLEC, which had the purpose to improperly increase the sales of Lipitor by promoting the drug's off-label use; (4) Thomson/PPS; and (5) outside marketing/sales firms employed by Pfizer (collectively, the "RICO Participants"), to promote the off-label use of Lipitor and extract illegal payments from third-party payors for Lipitor's off-label use.

137. The RICO enterprise is an ongoing and continuing business enterprise and each person within the enterprise has the common purpose to fraudulently increase sales of Lipitor: (1) inducing physicians to prescribe Lipitor to patients who will not benefit from the drug in order to unlawfully extract payments from third-party payors for off-label uses of Lipitor; and (2) capitalizing on Lipitor's inclusion in drug formularies for on-label uses to extract payments from third-party payors. Without the RICO enterprise, Pfizer could not have perpetuated its scheme to illegally promote the off-label use of Lipitor and extract improper payments from third-party payors for Lipitor's off-label use. During the relevant time period, each of the RICO Participants maintained a separate legal identity while operating the RICO enterprise. Pfizer continues to operate the RICO enterprise by instructing its agents to carry out the objectives of the RICO enterprise as identified herein.

138. Each of the RICO Participants has a systemic link through one another via contractual relationships, financial ties and the coordination of the RICO enterprise by Pfizer. Specifically, ESLM and Pfizer have systematic linkages as Pfizer fully funds the activities of ESLM and, as stated in the Operating Plan, uses ESLM to increase the sales of Lipitor. Following Pfizer's lead, ESLM promotes off-label use of Lipitor. NLEC, like ESLM, also maintains systematic linkages to Pfizer as Pfizer fully funds the activities of NLEC and, as stated

in the Operating Plan, uses NLEC to increase the sales of Lipitor. Following Pfizer's lead, NLEC promotes off-label use of Lipitor.

139. NLEC and ESLM knowingly helped Pfizer devise and implement the Company's scheme to illegally promote the off-label use of Lipitor.

140. Additionally, Pfizer and physician consultants employed by Pfizer to promote the off-label use of Lipitor and outside marketing/sales firms employed by Pfizer to promote the off-label use of Lipitor to fraudulently extract funds from third-party payors have systematic linkages. Pfizer contracts with and pays these physicians and outside marketing/sales firms to further the RICO enterprise's scheme to fraudulently increase the sales of Lipitor by promoting off-label uses of the drug. To obtain payment from Pfizer, these entities knowingly helped Pfizer devise and implement its illegal scheme to promote the off-label use of Lipitor.

#### **The RICO Participants' Pattern of Racketeering Activity**

141. The RICO Participants conducted and participated in the affairs of the RICO enterprise through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. The RICO Participants likely involved thousands of discrete instances of use of the U.S. mails or interstate wire facilities in furtherance of their scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

142. The RICO Participants' racketeering activities amounted to a common course of conduct with a similar pattern and purpose intended to deceive the Class. Each separate use of the U.S. mails and/or interstate wire facilities employed by the RICO Participants was related,

had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff and the Class. Each RICO Participant engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the RICO enterprise.

**The RICO Participants' Use of the U.S. Mails and Interstate Wire Facilities**

143. NIEC, ESLM, Thomson, PPS, Pfizer's physician consultants, and outside marketing/sales firms employed by Pfizer all knowingly promote Lipitor for off-label use to patients for whom drug therapy is not recommended under ATP III guidelines. The RICO Participants perpetrated the RICO enterprise by using the instrumentalities of interstate commerce. As a matter of necessity, in order to generate over \$12 billion of sales yearly, the RICO Participants communicated with one another about the RICO enterprise through the mails (including electronic mail) and the telephone. As detailed above, the enterprise employed a marketing scheme that involved thousands of newsletters, pamphlets, and other marketing material distributed nationwide, including website solicitations to consumers offering to send them Lipitor coupons over the mail; invitations to doctors to attend CME courses; and advertisements directed to consumers, doctors, and PBDMs.

144. Pfizer's illegal conduct and wrongful practices were carried out by several employees, physician consultants, ESLM, and NIEC. These entities worked across state boundaries and necessarily relied upon frequent transfers of documents and information, products, and funds by the U.S. mails and interstate wire facilities to further the goals of the RICO enterprise.

145. The nature and activities of the RICO enterprise was orchestrated by Pfizer from the Company's corporate headquarters in New York. Accordingly, Pfizer's scheme required its

headquarters to communicate directly and frequently by U.S. mails and by interstate wire facilities with the RICO Participants.

146. As manifested in the Operating Plan, Pfizer used NLEC and ESLM as an integral part of its marketing scheme to increase its sales of Lipitor for off-label uses. Pfizer exerted control over these organizations by encouraging their paid consultants to participate in CME courses and promote the off-label use of Lipitor. Pfizer also exerted control over these organizations by funding their activities and providing financial incentives to the organizations' leaders.

147. Many of the precise dates of the RICO enterprise's use of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the RICO Participants' books and records. Indeed, an essential part of the successful operation of the RICO enterprise alleged herein depended upon secrecy, and as alleged above, Pfizer took deliberate steps to conceal its wrongdoing. However, given the massive scope of Pfizer's scheme, Pfizer's use of the U.S. mails and interstate wire facilities to perpetrate the RICO enterprise involved thousands of communications.

#### **Pfizer's Motive In Creating And Operating The RICO Enterprise**

148. Pfizer's motive in creating and operating the RICO enterprise and directing the conduct and affairs of the RICO enterprise described herein was to fraudulently increase the off-label sales of Lipitor.

149. The RICO enterprise was designed to, and did, encourage others, including physicians, to advocate the off-label use of Lipitor knowing that third-party payors would rely on physician prescriptions for Lipitor's off-label use and pay for such improper uses of the drug.

### **Damages Caused by Pfizer's Scheme**

150. Pfizer's violations of federal law and its pattern of racketeering activity have directly and proximately caused the Named Plaintiffs and the Class injuries to their business or property as Plaintiffs have paid many hundreds of millions of dollars for Lipitor's off-label use.

151. Through the use of the RICO enterprise, Pfizer engaged in a pattern of racketeering activity including at least multiple episodes of mail fraud and wire fraud. Third-party payors were injured in their property by reason of these violations, by, among other things, having to unnecessarily pay hundreds of millions of dollars for Lipitor's off-label use. Pfizer and the RICO Participants engaged in numerous overt predicate fraudulent racketeering acts in furtherance of the conspiracy, and by reason of this third-party payors suffered injuries.

152. Pfizer's use of the mails and wires to perpetrate its fraud involved thousands of communications, including but not limited to, communications with the RICO Participants, physicians, consumers, and PBDMs relating to Pfizer's scheme to illegally promote Lipitor's off-label use.

153. Plaintiffs have been injured in their business and property by reason Pfizer's scheme in that Plaintiffs have paid hundreds of millions of dollars for Lipitor's off-label use.

154. Pfizer's scheme proximately caused injuries to third-party payors. It was foreseeable that doctors would respond to Pfizer's massive marketing blitz by prescribing Lipitor to patients who would not benefit from the drug and in violation of Lipitor's Label. A foreseeable consequence of Pfizer's scheme was to deceptively cause third-party payors to pay for medically unnecessary/off-label uses of Lipitor. Plaintiffs would not have made these unnecessary payments had Pfizer not engaged in its pattern of racketeering activity. By reason

of the unlawful acts engaged in by Pfizer, the Named Plaintiffs and the Class have suffered damages.

**Count II**  
**Unjust Enrichment**

155. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

156. Pfizer's scheme to promote the off-label use of Lipitor unjustly enriched the Company, to the detriment of Plaintiffs, by causing Pfizer to receive monetary benefits from third-party payors who were deceived into paying for Lipitor's off-label use.

157. Retention of Plaintiffs' funds by Pfizer for Lipitor's off-label use violates the fundamental principles of justice, equity, and good conscience.

158. Accordingly, Pfizer should be ordered to return any funds obtained as a result of its scheme to the Class.

**Count III**  
**Fraudulent Misrepresentation**

159. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

160. As detailed above, Pfizer made false statements of material fact regarding the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines pursuant to a scheme to cause third-party payors to pay for off-label uses of Lipitor.

161. Pfizer's false statements regarding the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines were knowingly made by the Company to induce physicians to prescribe Lipitor for off-label uses and to, in turn, induce third-party payors to pay for Lipitor's off-label use.

162. All Statewide Class Members similarly relied on Pfizer's misrepresentations promoting the off-label use of Lipitor by paying for Lipitor's off-label use.

163. The Statewide Class Members' reliance on Pfizer's misrepresentations promoting the off-label use of Lipitor was justifiable.

164. As a direct and proximate result of Pfizer's fraudulent misrepresentations, the Statewide Class Members suffered injuries for which monetary damages are sought.

**Count IV**  
**Negligent Misrepresentation**

165. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

166. As detailed above, Pfizer made false statements of material facts regarding the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines which caused third-party payors to pay for Lipitor's off-label use.

167. Pfizer's false statements regarding the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines were carelessly or negligently made by the Company without ascertaining the truth of such statements in order to induce physicians to prescribe Lipitor for off-label uses and to induce third-party payors to pay for Lipitor's off-label use.

168. During the Class Period, Pfizer had a duty to provide accurate information relating to Lipitor's on-label/FDA approved uses.

169. All Statewide Class Members similarly relied on Pfizer's misrepresentations promoting the off-label use of Lipitor by paying for Lipitor's off-label use.

170. The Statewide Class Members' reliance on Pfizer's misrepresentations promoting the off-label use of Lipitor was justifiable.

171. As a direct and proximate result of Pfizer's negligent misrepresentations, the Statewide Class Members suffered injuries for which monetary damages are sought.

**Count V**  
**Illinois' Consumer Fraud and Deceptive Business Practices Act**  
**815 ILL. COMP. STAT. 505/1 *et seq.* (the "Act")**

172. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

173. As detailed above, Pfizer's scheme to illegally promote the off-label use of Lipitor by mischaracterizing the federally approved uses of the drug and the recommendations contained in the ATP III guidelines, caused third-party payors to pay for off-label uses of Lipitor. Pfizer's scheme is a deceptive act or practice which violates the provisions of the Act.

174. Pfizer intended that third-party payors rely on its deception, which occurred during the conduct of a trade or commerce, and pay for off-label uses of Lipitor.

175. The Statewide Class Members were deceived by Pfizer's deception and paid for Lipitor's off-label use, causing the Statewide Class Members to suffer actual damages.

176. As a direct and proximate result of Pfizer's deception and violations of the Act, the Statewide Class Members suffered injuries for which monetary damages are sought.

**PRAYER FOR RELIEF**

WHEREFORE, the Named Plaintiffs demand judgment on behalf of themselves and similarly situated third-party payors as follows:

A. Awarding Plaintiffs compensatory damages against Pfizer in an amount to be determined at trial, together with prejudgment interest at the maximum rate allowable by law;

B. Awarding Plaintiffs treble damages, costs of this suit, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c);

- C. Awarding Plaintiffs any amount by which Pfizer has been unjustly enriched;
- D. Awarding Plaintiffs punitive or exemplary damages in an appropriate amount to be determined at trial;
- E. Awarding Plaintiffs the costs of this suit, including reasonable attorneys' fees and other disbursements;
- F. Enjoining Pfizer from continuing the illegal and deceptive activities alleged herein; and
- G. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

**JURY DEMAND**

Named Plaintiffs demand a trial by jury.

DATED: March 31, 2006

Respectfully submitted,

CAVANAGH & O'HARA )



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## **EXHIBIT F**

**UNITED STATES DISTRICT COURT  
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<p><b>SOUTHERN ILLINOIS LABORERS' AND EMPLOYERS HEALTH AND WELFARE FUND; NECA-IBEW WELFARE TRUST FUND; MIDWESTERN TEAMSTERS HEALTH AND WELFARE FUND; THE WELFARE FUND OF TEAMSTERS LOCAL UNION 863; PLUMBERS &amp; PIPEFITTERS LOCAL UNION 630 WELFARE TRUST FUND; CLEVELAND BAKERS AND TEAMSTERS HEALTH AND WELFARE FUND; ELECTRICAL WORKERS BENEFIT TRUST FUND; FIRE &amp; POLICE RETIREE HEALTH CARE FUND, SAN ANTONIO, LABORERS' DISTRICT COUNCIL BUILDING AND CONSTRUCTION HEALTH AND WELFARE FUND; LABORERS' DISTRICT COUNCIL HEAVY AND HIGHWAY UTILITY HEALTH AND WELFARE FUND, NEW YORK CITY POLICE SERGEANTS BENEVOLENT ASSOCIATION HEALTH &amp; WELFARE FUNDS, and SIDNEY HILLMAN HEALTH CENTER OF ROCHESTER individually, and On Behalf of All Others Similarly Situated,</b></p> <p style="text-align: center;"><b>Plaintiffs,</b></p> <p style="text-align: center;"><b>v.</b></p> <p><b>PFIZER INC.,</b></p> <p style="text-align: center;"><b>Defendant.</b></p>	<p><b>CIVIL ACTION No. 06-CV-1818</b></p> <p><b>JUDGE JOHN W. DARRAH</b></p> <p><b>MAGISTRATE JUDGE GERALDINE SOAT BROWN</b></p> <p><b>JURY TRIAL DEMANDED</b></p> <p><b><u>AMENDED CLASS ACTION COMPLAINT</u></b></p>
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# **Table of Contents**

	<b>Page</b>
I. NATURE OF THE ACTION .....	1
II. PARTIES .....	5
III. JURISDICTION AND VENUE .....	9
IV. BACKGROUND .....	10
A. Pfizer's Marketing History .....	10
B. The Food And Drug Administration's Prohibition Of Off-Label Marketing .....	12
C. The ATP III Guidelines .....	14
1. Summary Of The ATP III Guidelines.....	14
2. The Purpose Behind The ATP III Guidelines.....	17
D. Lipitor's On Label Indications.....	19
E. Pfizer's Scheme Defrauds Medicare and Medicaid.....	21
F. Pfizer Defrauds Third-Party Payors.....	23
V. PFIZER'S SCHEME .....	24
A. Pfizer's Scheme Targets A Defined Group of Persons.....	24
B. Pfizer's Illegal Promotion Of Lipitor Targets Pharmacy Benefit Decision Makers, Physicians, And Consumers .....	26
1. Pfizer Illegally Promotes The Off-Label Use Of Lipitor To Pharmacy Benefit Decision Makers.....	26
2. Pfizer Illegally Induces Physicians To Prescribe Lipitor For Off-Label Uses.....	29
3. Pfizer Illegally Promotes Lipitor's Off-Label Use To Consumers.....	34
C. Pfizer's Scheme To Promote The Off-Label Use Of Lipitor Downplays The Significance of TLC.....	35

D.	Pfizer's Illegal Promotion Of Lipitor's Off-Label Use Is Orchestrated At The Highest Levels Of The Company And Is Crucial To The Company's Business Plan .....	36
E.	Pfizer Improperly Utilizes Third-Parties To Promote Its Fraudulent Scheme .....	38
1.	Pfizer Used The National Lipid Education Council To Further Its Scheme To Promote The Off-Label Use Of Lipitor.....	38
2.	Pfizer Used The Emerging Science Of Lipid Management To Further Its Scheme To Promote The Off-Label Use Of Lipitor .....	41
3.	Pfizer Used Independent Consultants To Promote The Off-Label Use Of Lipitor .....	45
VI.	CLASS ACTION ALLEGATIONS .....	37
VII.	COUNTS.....	39

Plaintiffs Southern Illinois Laborers' and Employers Health and Welfare Fund ("Southern Illinois L&E"), NECA-IBEW Welfare Trust Fund ("NECA-IBEW"), and Midwestern Teamsters Health and Welfare Fund ("Midwestern Teamsters H&W"), Welfare Fund of Teamsters Local Union 863 ("Local 863 Fund"), Plumbers & Pipefitters Local Union 630 Welfare Trust Fund ("Plumbers & Pipefitters Fund"), Cleveland Bakers and Teamsters Health and Welfare Fund ("CB&T Fund"), Electrical Workers Benefit Trust Fund ("EWBTF"), Fire & Police Retiree Health Care Fund, San Antonio ("F&P Retiree Health Care Fund"), Laborers' District Council Building and Construction Health and Welfare Fund ("Building and Construction Health and Welfare Fund"), Laborers' District Council Heavy and Highway Utility Health and Welfare Fund ("Heavy and Highway Health and Welfare Fund"), Sidney Hillman Health Center of Rochester ("Sidney Hillman"), and New York City Police Sergeants Benevolent Association Health & Welfare Funds ("NYC Sergeants Fund") (collectively, "Named Plaintiffs"), on behalf of themselves and other third-party payors, including state medical assistance programs (including, *inter alia*, state Medicaid programs and state employee benefit plans) for all fifty states and the District of Columbia, that paid any portion of the purchase price for Lipitor® (atorvastatin calcium) ("Lipitor") when used under circumstances not specified on its label (collectively, "Plaintiffs") between January 1, 2002 through the present ("Class Period"), by their attorneys, hereby allege, upon knowledge with respect to facts concerning themselves, and as to all other matters, which generally concern facts not in Named Plaintiffs' possession, upon information and belief, as follows:

## **I. NATURE OF THE ACTION**

1. This is a class action lawsuit asserting claims against defendant Pfizer Inc. ("Pfizer" or the "Company"), on behalf of a proposed nationwide class of health and welfare funds and third-party/payors (collectively "third-party payors") that paid any portion of the

purchase price for Pfizer's cholesterol-lowering drug Lipitor's off-label use. The complaint, on behalf of a nationwide class (including state medical assistance programs), asserts claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), for civil conspiracy, for unjust enrichment, and for an accounting of Pfizer's gains from the off-label sales of Lipitor. Additionally, Named Plaintiffs assert the following claims on behalf of sub-classes of third-party payors (including state medical assistance programs) from their respective states:

- Plaintiffs Southern Illinois L&E, NECA-IBEW, and Midwestern Teamsters H&W also bring this action on behalf of a sub-class of third-party payors located in Illinois that paid any part of Lipitor's purchase price for its off-label use ("Illinois Statewide Class"). The Illinois Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and under Illinois' Consumer Fraud and Deceptive Business Practices Act, 815 ILL. COMP. STAT. 505/1 *et seq.*;
- Plaintiff Local 863 Fund also brings this action on behalf of a sub-class of third-party payors located in New Jersey that paid any part of Lipitor's purchase price for its off-label use ("New Jersey Statewide Class"). The New Jersey Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and under the New Jersey Consumer Fraud Act ("CFA"), N.J.S.A. §§ 56:8-1 *et seq.*;
- Plaintiff Plumbers & Pipefitters Fund also brings this action on behalf of a sub-class of third-party payors located in Florida that paid any part of Lipitor's purchase price for its off-label use ("Florida Statewide Class"). The Florida Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and under Florida's Deceptive and Unfair Trade Practices Act ("DUTPA"), FLA. STAT. §§ 501.201, *et seq.*;

- Plaintiff CB&T Fund also brings this action on behalf of a sub-class of third-party payors located in Ohio that paid any part of Lipitor's purchase price for its off-label use ("Ohio Statewide Class"). The Ohio Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and under Ohio's Consumer Sales Practices Act, OHIO REV. CODE ANN. §§ 1345.01, *et seq.* ("CSPA");
- Plaintiff EWBTF also brings this action on behalf of a sub-class of third-party payors located in Indiana that paid any part of Lipitor's purchase price for its off-label use ("Indiana Statewide Class"). The Indiana Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and under Indiana's Deceptive Consumer Sales Act ("DCSA"), Ind. Code §§ 24-5-0.5-1, *et seq.*;
- Plaintiff F&P Retiree Health Care Fund also brings this action on behalf of a sub-class of third-party payors located in Texas that paid any part of Lipitor's purchase price for its off-label use ("Texas Statewide Class"). The Texas Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and under Texas' Deceptive Trade Practices and Consumer Protection Act, TEX. BUS. & COM. § 17.41-63 ("DTPA"); and
- Plaintiffs Laborers' District Council Building and Construction Health and Welfare Fund and Laborers' District Council Heavy and Highway Utility Health and Welfare Fund also bring this action on behalf of a sub-class of third-party payors located in Pennsylvania that paid any part of Lipitor's purchase price for its off-label use ("Pennsylvania Statewide Class"). The Pennsylvania Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and under

Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTP/CPL"), 73 PA. CONS. STAT. ANN. §§ 201-1 *et seq.*

- Plaintiffs NYC Sergeants Fund and Sidney Hillman also bring this action on behalf of a sub-class of third-party payors located in New York that paid any part of Lipitor's purchase price for its off-label use ("New York Statewide Class"). The New York Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and violations of N.Y. GEN. BUS. LAW § 349 (Making Deceptive Acts and Practices Unlawful), and N.Y. GEN. BUS. LAW § 350 (Making False Advertising Illegal).

2. The claims against Pfizer arise from the Company's illegal "off-label" promotion of Lipitor for uses that are contrary to the drug's Food and Drug Administration ("FDA") approved uses.

3. For at least the past four years, Pfizer has illegally promoted Lipitor to the public and prescribing physicians by promoting the off-label use of the drug. Pfizer's scheme relied on fraudulently misrepresenting the treatment guidelines established by the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel) ("ATP III") and suggesting its "off-label" marketing of Lipitor actually conformed with ATP III's guidelines. Pfizer has done this through a nationwide campaign that promoted the use of Lipitor in violation of ATP III's guidelines for the initiation of drug therapy. Pfizer also employed purported "independent" third-parties, which were fully funded by Pfizer and/or received other incentives from the Company, to promote Lipitor's off-label use. These third-parties furthered Pfizer's scheme by promoting the off-label use of Lipitor to physicians under the guise of providing

physicians with educational information concerning the use of statin drugs. Pfizer also trained its own internal sales force to misrepresent the ATP III guidelines and Lipitor's approved uses.

4. Pfizer's scheme has been incredibly successful for the Company. According to the Company's annual report for 2005, Lipitor "is the most widely used treatment for lowering cholesterol and the best-selling pharmaceutical product of any kind in the world reaching over \$12 billion in sales in 2005." However, approximately 54 percent, or up to \$6.581 billion a year of Lipitor's sales flow from the illegal scheme set forth below. Over the period from January 1, 2002 to October 1, 2006, Plaintiffs estimate Pfizer's unlawful sales of Lipitor at \$31.278 billion.

## II. PARTIES

5. Plaintiff Southern Illinois L&E is an employee benefit fund administered pursuant to the terms and provisions of the Agreement and Declaration of Trust creating Southern Illinois L&E and is required to be maintained and administered in accordance with the provisions of the Labor Management Relations Act of 1947, and the Employee Retirement Income Security Act of 1974 (as amended), 29 U.S.C. §§ 1001 *et seq.* The address and place of business of Southern Illinois L&E is 2035 Washington Avenue, Cairo, Illinois 62914. Southern Illinois L&E covers the cost of health care for eligible participants, including paying for medically necessary uses of drugs. During the Class Period, Southern Illinois L&E paid for Lipitor under circumstances not specified on its FDA-approved label on behalf of persons participating in Southern Illinois L&E's healthcare plan.

6. Plaintiff NECA-IBEW is an employee benefit fund administered pursuant to the terms and provisions of the Agreement and Declaration of Trust creating NECA-IBEW and is required to be maintained and administered in accordance with the provisions of the Labor Management Relations Act of 1947, and the Employee Retirement Income Security Act of 1974 (as amended), 29 U.S.C. §§ 1001 *et seq.* The address and place of business of NECA-IBEW is

2120 Hubbard Drive, Decatur, Illinois 62526. NECA-IBEW covers the cost of health care for eligible participants, including paying for medically necessary uses of drugs. During the Class Period, NECA-IBEW paid for Lipitor under circumstances not specified on its FDA-approved label on behalf of persons participating in NECA-IBEW's healthcare plan.

7. Plaintiff Midwestern Teamsters H&W is an employee benefit fund administered pursuant to the terms and provisions of the Agreement and Declaration of Trust creating Midwestern Teamsters H&W and is required to be maintained and administered in accordance with the provisions of the Labor Management Relations Act of 1947, and the Employee Retirement Income Security Act of 1974 (as amended), 29 U.S.C. §§ 1001 *et seq.* The address and place of business of Midwestern Teamsters H&W is Tedro & Associates, Inc., 2160 Foster Avenue, Wheeling, Illinois 60090. Midwestern Teamsters H&W covers the cost of health care for eligible participants, including paying for medically necessary uses of drugs. During the Class Period, Midwestern Teamsters H&W paid for Lipitor under circumstances not specified on its FDA-approved label on behalf of persons participating in Midwestern Teamsters H&W's healthcare plan.

8. Plaintiff Local 863 Fund is a Taft-Hartley welfare fund created pursuant to the Employee Retirement Income Security Act ("ERISA") 29 U.S.C. §§ 1001, *et seq.* Local 863 Fund is funded by contributions of participating employers and provides health and welfare benefits to covered employees and retirees. The address and place of business of Local 863 Fund is 209 Summit Road, Mountainside, New Jersey 07092. Local 863 Fund covers the cost of healthcare for eligible participants, including paying for medically necessary uses of drugs. During the Class Period, Local 863 Fund paid for Lipitor under circumstances not specified on its FDA-approved label on behalf of persons participating in Local 863 Fund's healthcare plan.

9. Plaintiff Plumbers & Pipefitters Fund is a common law trust established pursuant to collective bargaining agreement between Plumbers and Pipefitters Local Union 630 and various employers. It was established on June 29, 1970. The address and principal place of business of Plumbers & Pipefitters Fund is 2801 Ponce DeLeon, Suite 750, Coral Gables Florida 33134. The Plumbers & Pipefitters Fund covers the cost of healthcare for eligible participants, including paying for medically necessary uses of drugs. During the Class Period, Plumbers & Pipefitters Fund paid for Lipitor under circumstances not specified on its FDA-approved label on behalf of persons participating in the Plumbers & Pipefitters Fund's healthcare plan.

10. Plaintiff CB&T Fund is a Taft Hartley Multiemployer Trust Fund established on May 1, 1990. The address and principal place of business of CB&T Fund is 9665 Rockside Road, Suite C, Cleveland, Ohio 44125-6233. CB&T Fund covers the cost of healthcare for eligible participants, including paying for medically necessary uses of drugs. During the Class Period, CB&T Fund paid for Lipitor under circumstances not specified on its FDA-approved label on behalf of persons participating in CB&T Fund's healthcare plan.

11. Plaintiff EWBTF is a Taft Hartley Fund which was established on January 1, 1964. The address and principal place of business of EWBTF is 1828 North Meridian Street, Suite 103, Indianapolis, IN 46202-1404. EWBTF covers the cost of healthcare for eligible participants and retirees residing primarily in Indiana, including paying for medically necessary uses of drugs. During the Class Period, EWBTF paid for Lipitor under circumstances not specified on its FDA-approved label on behalf of persons participating in EWBTF's healthcare plan.

12. Fire & Police Retiree Health Care Fund, San Antonio is a Voluntary Employee Benefit Account ("VEBA"). F&P Retiree Health Care Fund covers the cost of healthcare for

eligible participants and retirees residing primarily in Texas, including paying for medically necessary uses of drugs. During the Class Period, F&P Retiree Health Care Fund paid for Lipitor under circumstances not specified on the drug's FDA-approved label on behalf of persons participating in F&P Retiree Health Care Fund.

13. Plaintiff Laborers' District Council Building and Construction Health and Welfare Fund is a trust fund established and maintained pursuant to the provisions of Section 302(c)(5) of the Labor Management Relations Act ("LMRA"), 29 U.S.C. § 186(c)(5), and an employee welfare benefit plan under the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §§ 1001 *et seq.* Building and Construction Health and Welfare Fund is located in Philadelphia, PA and covers the cost of healthcare for eligible participants, including paying for medically necessary uses of drugs. During the Class Period, Building and Construction Health and Welfare Fund paid for Lipitor under circumstances not specified on its FDA-approved label on behalf of persons participating in Building and Construction Health and Welfare Fund's healthcare plan.

14. Plaintiff Laborers' District Council Heavy and Highway Utility Health and Welfare Fund is a trust fund established and maintained pursuant to the provisions of Section 302(c)(5) of LMRA, 29 U.S.C. § 186(c)(5), and an employee welfare benefit plan under ERISA, 29 U.S.C. §§ 1001 *et seq.* Heavy and Highway Health and Welfare Fund has its principal place of business in Philadelphia, PA and covers the cost of healthcare for eligible participants, including paying for medically necessary uses of drugs. During the Class Period, Heavy and Highway Health and Welfare Fund paid for Lipitor under circumstances not specified on its FDA-approved label on behalf of persons participating in Heavy and Highway Health and Welfare Fund's healthcare plan.

15. Plaintiff NYC Sergeants Fund is a self insured union Health and Welfare Fund with 33,000 members and dependents. NYC Sergeants Fund maintains its principal place of business at 35 Worth Street, New York, NY 10013, and provides pharmaceutical, dental, and optical benefits to eligible participants, including paying for medically necessary uses of drugs. During the Class Period, NYC Sergeants Fund paid for Lipitor under circumstances not specified on its FDA-approved label on behalf of persons participating in NYC Sergeants Fund's healthcare plan.

16. Plaintiff Sidney Hillman is a Taft-Hartley Fund that is a New York State Not for Profit Corporation. Sidney Hillman was established in 1960 and services members primarily in Rochester, New York. Sidney Hillman also operates a pharmacy as a benefit to its members. During the Class Period, Sidney Hillman paid for Lipitor under circumstances not specified on its FDA-approved label on behalf of persons participating in Sidney Hillman's healthcare plan.

17. Defendant Pfizer is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. The Company engages in the discovery, development, manufacturing, and marketing of prescription medicines for humans and animals, as well as consumer healthcare products worldwide. Pfizer reported over \$51 billion in revenues for 2005.

### **III. JURISDICTION AND VENUE**

18. This Court has subject matter jurisdiction over this class action pursuant to the Class Action Fairness Act of 2005, Pub.L. 109-2, § 7, 119 Stat. 13. The Class Action Fairness Act, amended 28 U.S.C. § 1332 to add subsection (d) which, as here, confers diversity jurisdiction upon this Court because members of the class are citizens from a state different from the Defendant's state and the aggregate amount in controversy exceeds five million dollars (\$5,000,000). The Court has personal jurisdiction over the parties because the Named Plaintiffs

are located and operating in this state (or otherwise submit to the jurisdiction of the Court) and Pfizer systematically and continuously conducts business in this state, including marketing, advertising, and selling drugs such as Lipitor to residents in this state.

19. The Court also has jurisdiction under 28 U.S.C. § 1331 as Named Plaintiffs' RICO claims arise under 18 U.S.C. § 1962.

20. Venue is proper in this District under 28 U.S.C. § 1391 because the Defendant engaged in substantial conduct relevant to several Named Plaintiffs' claims within this District and caused harm to certain Plaintiffs residing within this District.

#### IV. BACKGROUND

##### A. Pfizer's Marketing History

21. Pfizer's single most successful prescription drug is Lipitor. Lipitor is a statin drug that was approved by the FDA for sale to the public on December 18, 1996. Statins reduce cholesterol levels by blocking the body's production of certain enzymes that are needed to produce cholesterol.

22. In 2001, Pfizer began a national marketing campaign to improperly expand by millions the population for whom Lipitor is prescribed by illegally promoting the off-label and medically unnecessary use of the drug. Since then, Pfizer has been cited twice by the FDA for improperly marketing Lipitor by, *inter alia*, downplaying both the harmful side effects of the drug and the importance of diet and exercise in lowering cholesterol. Despite its troubles with the FDA, Pfizer's marketing of Lipitor has been very successful. According to Pfizer's public filings, annual sales of Lipitor have increased from \$5.03 billion in 2000 to \$12.1 billion in 2005, an increase of 140%. Pfizer's campaign has made Lipitor the best selling drug in the United States and the world's first \$12 billion drug. Between 2001 and 2005, Lipitor has generated more than \$46 billion in revenue for Pfizer.

23. This is not, however, the first time that Pfizer has been caught engaging illegally marketing its drugs. Indeed, just four years ago, Pfizer got caught defrauding Medicare and Medicaid out of tens of millions of dollars by misrepresenting the “best price” the Company offered for Lipitor, and thereby overcharging the Medicare and Medicaid for millions of Lipitor prescriptions. Ultimately, Pfizer agreed to pay \$49 million to settle the charges, and to enter into a five-year Corporate Integrity Agreement (“CIA”) with the Department of Health and Human Services’ Office of Inspector General that was designed to require strict scrutiny of Pfizer’s marketing and sales practices and to prevent Pfizer’s looting of the Medicaid Rebate program (the “Lipitor Settlement”).

24. But Pfizer’s illegal marketing did not stop there. In 2004, less than two years after agreeing to the CIA, Pfizer was caught illegally marketing Neurontin, an anti-seizure and pain medication. Specifically, in a scheme remarkably similar to the scheme outlined below, Pfizer illegally marketed Neurontin for uses not indicated on the drug’s FDA-approved label. To settle criminal and civil charges relating to these illegal off-label marketing practices, Pfizer agreed to pay \$430 million, and to enter into a new Corporate Integrity Agreement (“CIA II”) that superseded the original CIA, and was supposed to ensure Pfizer’s compliance with all applicable marketing regulations, including restrictions on the off-label marketing of drugs (the “Neurontin Settlement”).

25. But old habits die hard. And, as detailed below, Pfizer has continued, to this day, to illegally market its products with an intent to maximize profits regardless of the applicable laws and regulations. Indeed, Pfizer’s deliberate efforts to flout the legal restrictions on its marketing practices evidences a belief that the \$479 million it has been required to pay to date as

a result of its illegal conduct is but a small price to pay for marketing that has brought the Company over \$46 billion on sales of Lipitor alone.

26. As the Neurontin Settlement and the CIA II make clear, however, Pfizer is well aware of the legal restrictions prohibiting off-label marketing, and the legal implications of a drug's FDA-approved label. As discussed below, Pfizer's marketing of Lipitor was specifically designed to encourage the use of Lipitor by a group identified by the FDA itself as *not* being candidates for treatment with cholesterol-lowering drugs. By promoting the use of Lipitor by these individuals, Pfizer knowingly marketed Lipitor for off-label use, in violation of the CIA II, in violation of federal law, and in violation of state laws prohibiting illegal marketing practices.

**B. The Food And Drug Administration's Prohibition Of Off-Label Marketing**

27. A manufacturer may distribute a drug only if it is approved by the FDA. *See* 21 U.S.C. § 355(a). In order for the FDA to approve a drug, the manufacturer must show that a drug is "safe for use" for all "conditions prescribed, recommended, or suggested" on a drug's label. 21 U.S.C. § 355(d).

28. A drug is considered misbranded if its label does not contain, *inter alia*, "[s]tatements of all conditions, purposes, or uses for which such drug is intended." 21 C.F.R. § 201.5. *See also* 21 U.S.C. § 331(a) (prohibiting the introduction of misbranded drugs into interstate commerce); 21 U.S.C. § 352(f) (stating that a drug is misbranded if it does not contain "adequate directions for use"). The term "intended" in 21 C.F.R. § 201.5 refers to "the objective intent of the persons legally responsible for labeling drugs [e.g., the manufacturer]." 21 C.F.R. § 201.128. Therefore, if a manufacturer intends that a drug be used for a certain purpose, information about that purpose must be on the drug's label and approved as safe by the FDA.

29. Where a manufacturer directly advertises a drug for a particular use, that use is considered an intended use. *See* 21 C.F.R. § 201.128 ("[I]ntent may, for example, be shown by

labeling claims, advertising matter, or oral or written statements by . . . [manufacturers] or their representatives.”). Therefore, if a drug’s manufacturer advertises uses not on its FDA-approved label, the drug is considered misbranded and its distribution in interstate commerce is prohibited. *See* 21 U.S.C. § 331(a) and (d).

30. Furthermore, depending on the circumstances, if a manufacturer promotes off-label use indirectly – for example, by sponsoring continuing medical education (“CME”) courses that promote off-label use – such off-label use may be considered an intended use if the manufacturer intended that the drug be used for off-label purposes. *See* 21 C.F.R. § 201.128 (“It may be shown by the circumstances that the article is, with the knowledge of . . . [the manufacturer] or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.”).

31. However, the FDA has created certain avenues for manufacturers to communicate off-label information to doctors. A manufacturer may forward off-label information in medical and scientific publications to a physician in response to an unsolicited request. *See* 21 U.S.C. § 360aaa-6.

32. Also, manufacturers may disseminate off-label information to a physician, pharmacy benefit manager, health insurance issuer, group health plan, or Federal or State governmental agency if the manufacturer, *inter alia*, discloses that the use is off-label and provides the disseminated material to the FDA. *See* 21 U.S.C. §§ 360aaa(a)-(c); 360aaa-1.

33. Notwithstanding the FDA’s regulation of manufacturers, the FDA does not regulate how doctors prescribe drugs. Physicians may prescribe approved drugs for any purpose that he or she sees fit.

34. The FDA has approved Lipitor for use only in accordance with the ATP III guidelines (described below). Accordingly, any marketing of Lipitor that does not conform with the guidelines set forth in ATP III is considered off-label marketing and violates FDA regulations.

### **C. The ATP III Guidelines**

#### **1. Summary Of The ATP III Guidelines**

35. The ATP III guidelines, which were developed based upon years of analysis and discussion by NCEP, are incorporated onto Lipitor's Prescribing Information (revised September 2005) (the "Label") and indicate the on-label uses of the drug.

36. ATP III is an evidence-based set of guidelines on cholesterol management that "extensively analyzed the results of recent clinical trials." ATP III at I-1. ATP III's "major goals were to review the literature objectively and to document and display the scientific evidence for ATP III recommendations." *Id.* The initial guidelines were known as ATP I and ATP II and were adopted in the 1990s. The ATP III guidelines updated the ATP II guidelines in 2001, and were recently updated in 2004.

37. The ATP III report advises physicians on the appropriate stage to initiate drug therapy as opposed to therapeutic lifestyle changes ("TLC"), which include changes to diet and exercise. The ATP III guidelines, which are incorporated into Lipitor's Label, have been adopted by third-party payors as the applicable criteria under which they will pay for Lipitor.

38. ATP III's guidelines set goal low-density lipoprotein ("LDL") levels based on the onset of coronary heart disease ("CHD"), the number of risk factors that may lead to CHD, and a patient's 10-year risk of developing CHD. Risk factors include cigarette smoking, hypertension, low HDL-C (high-density lipoprotein cholesterol), family history of premature CHD, age, and gender.

39. According to the ATP III guidelines, patients with CHD or CHD risk equivalents have an LDL goal of less than 100 mg/dL; patients with two or more risk factors have an LDL goal of less than 130 mg/dL; and patients with one (or less) risk factors have an LDL goal of less than 160 mg/dL. *See* ATP III at IV-2-4. *See also* Label at 12 table 6.

40. However, the goal LDL levels in the ATP III report are not levels that trigger the use of drug therapy.

41. The ATP III guidelines recommend use of drug therapy to achieve LDL goals based on the following four factors: (1) a patient's LDL level; (2) whether a patient is suffering from CHD; (3) the number of risk factors a patient faces for developing CHD; and (4) a patient's 10-year probability for developing CHD.

42. Based on these factors, the ATP III report segregates patients with high LDL cholesterol into two categories: (1) patients that can be treated with TLC alone; and (2) patients for whom drug therapy may be considered in conjunction with TLC.

43. According to the ATP III report, patients with CHD have a goal LDL of less than 100 mg/dL and TLC should be initiated when the LDL is greater than or equal to 100 mg/dL. For these patients, drug therapy is recommended if their LDL level is equal to or greater than 130 mg/dL and is optional if their LDL is between 100 mg/dL and 129 mg/dL. The 2004 updates recommend drug therapy when the patient's LDL is above 100 mg/dL. The updates also create a group of "very high risk" patients with an LDL goal of 70 mg/dL.

44. Patients with multiple (2 or more) risk factors have an LDL goal of less than 130 mg/dL. For these patients, TLC should be initiated if their LDL level is greater than or equal to 130 mg/dL. If a patient's 10-year CHD risk is between 10% and 20% drug therapy may be considered if the patient's LDL level is greater than or equal to 130 mg/dL. The 2004 updates

provide an optional goal of 100 mg/dL and also provide the option of using drug therapy to reach this goal.

45. Significantly, however, for a patient with multiple risk factors and a 10-year CHD risk of less than 10%, drug therapy can only be considered if the patient's LDL is greater than or equal to 160 mg/dL, well above their LDL goal of 130 mg/dL. *The 2004 updates did not modify the ATP III guidelines for this group.* According to NCEP, there are 14.6 million people in this group who do not need drug therapy (those with multiple CHD risk factors and LDL levels between 130 mg/dL and 159 mg/dL). This group is the primary target of Pfizer's scheme.

46. The ATP III guidelines clearly articulate that patients with multiple risk factors and less than a 10% chance of developing CHD are not candidates for drug therapy unless their LDL is greater than or equal to 160 mg/dL:

The LDL-cholesterol goal for multiple risk factors and 10-year risk <10 percent also is <130 mg/dL. However, LDL-lowering drugs are not to be considered unless LDL cholesterol remains  $\geq 160$  mg/dL on TLC. When 10-year risk is <10 percent, cost-effectiveness of drug therapy begins to erode, especially when the LDL-cholesterol level remains in the range of 130 to 159 mg/dL and other risk factors are appropriately controlled. On the other hand, when LDL-cholesterol concentrations  $\geq 160$  mg/dL occur with multiple (2+) risk factors, longterm (>10-year) risk for CHD is relatively high. Thus, drug therapy deserves consideration. Of course, costs and side effects of drugs must also be taken into account when contemplating lifetime drug therapy.

ATP III at VI-6 (emphasis added). The 2004 updates did not make any changes to this group.

47. Finally, patients who are not suffering from CHD and have one or less risk factor have a goal LDL of less than 160 mg/dL. For this group, ATP III recommends TLC if the patient's LDL is greater than or equal to 160 mg/dL and recommends that drug therapy may be initiated if the patient's LDL level is greater than or equal to 190 mg/dL, with an option to treat with drugs when LDL is between 160 mg/dL and 189 mg/dL.

48. For all patient groups, ATP III recommends that TLC, including changes in diet and increased exercise, be tried before starting drug therapy.

## 2. The Purpose Behind The ATP III Guidelines

49. The ATP III guidelines are promulgated on both a risk/benefit and cost/benefit analysis that weighs the health risks and the financial costs of statin therapy against the potential benefits statins provide to patients.

50. The use of statins expose patients to several adverse health risks. Some practitioners have stated that 20% of patients using statins experience some side effects. See John Fauber, *Doubts Raised Over Drugs For Cholesterol*, MILWAUKEE JOURNAL SENTINEL, Mar. 27, 2004.

51. Lipitor's Label itself includes a laundry list of potentially adverse consequences that may result from the drug's use. According to Lipitor's Label, patients using Lipitor face an increased risk of suffering adverse reactions including pain, digestive problems, respiratory problems, rashes, and potentially fatal complications of the liver and skeletal muscle.

52. Moreover, Lipitor should not be used by childbearing women as the drug may injure fetuses: "[LIPITOR] SHOULD BE ADMINISTERED TO WOMEN OF CHILDBEARING AGE ONLY WHEN SUCH PATIENTS ARE HIGHLY UNLIKELY TO CONCEIVE AND HAVE BEEN INFORMED OF THE POTENTIAL HAZARDS." Lipitor Label at 13 (emphasis in original).

53. The health risks of statin use are far-reaching. Statin users have reported intense pain that "engulf[ed] every muscle" in the body and pain which continued years after terminating statin therapy. John Fauber, *Doubts Raised Over Drugs For Cholesterol*, MILWAUKEE JOURNAL SENTINEL, Mar. 27, 2004. Others have linked Lipitor use to cognitive problems such as memory loss. *Id.* A 2003 article by Maryann Napoli states: "Thousands of cases of memory dysfunction

have been reported to the FDA's Medwatch program . . . but after two years, the agency still hasn't acted. And most practicing physicians are unaware of the problem. *Lipitor is not the only statin linked to this side effect.* . . ." Maryann Napoli, *Cholesterol Skeptics and the Bad News About Statin Drugs*, CENTER FOR MEDICAL CONSUMERS, June 2003 (emphasis added).

54. The health risks associated with statin use was one factor used by the ATP III Panel to promulgate the recommended uses of statin drugs. Scott Grundy, M.D., Ph.D., who served as the Chair of NCEP ATP III, states: "[S]tatins, like all drugs, can have side effects, and care must be taken in the use on persons with predisposing conditions. Moreover, it seems unwise to use statins outside current cholesterol-management guidelines." Scott M. Grundy, *The Issue of Statin Safety: Where Do We Stand?*, CIRCULATION, June 14, 2005 (emphasis added). Dr. Grundy cites to the ATP III guidelines in support of his statement.

55. In addition to the health risks, statins also impose monetary costs on society's already strained healthcare system. ATP III's cost/benefit balancing regarding the use of statins is reflected in the following comments:

The widespread use of LDL-lowering drugs, although potentially effective in reducing the burden of CHD in the United States, would be costly. The fundamental rationale for assessment of economic consequences of LDL-lowering drugs is the reality that resources are limited, whereas demand for medical therapies always exceeds available public resources. Consequently, difficult choices often must be made among potentially beneficial interventions. Resources are best allocated according to potential alternative uses. Evidence of efficacy and safety of drug therapy, a requirement for clinical intervention, is insufficient to make recommendations for drug use in a cost-constrained society. This is particularly true when many millions of persons are potential recipients of the therapy. Limited resources should be targeted to where they provide the greatest health benefits. One of the major objectives of cost-effectiveness analysis is to facilitate patient selection so that incremental benefits are greatest relative to incremental costs. Thus, for LDL-lowering therapy to be widely used in the U.S. population, it must be cost-effective by current standards.

ATP III at II-55. Therefore, the guidelines were carefully constructed to optimize the use of cholesterol lowering drugs.

56. In essence, therefore, the ATP III guidelines reflect the results of a detailed analysis that weighed the health risks associated with the use of statins (including Lipitor) against the benefits that can be realized through drug therapy in terms of avoiding the onset of CHD.

57. Pfizer simply cast aside ATP III's careful cost/benefit balancing and devised a scheme to market the drug to people for whom the costs and risks did not outweigh the benefits. A Pfizer slide presentation presented to Pfizer marketers titled "Lipitor POA 1 CEC Session" stated, on slide 47, that "LIPITOR [is] not perceived as a cost-effective means of getting patients to goal." The presentation then instructed marketers to: "[d]emonstrate that LIPITOR meets expanding cholesterol management needs while providing great value to customers." (emphasis added).

#### **D. Lipitor's On Label Indications**

58. Lipitor's Label adopts and incorporates the ATP III recommendations for initiating drug therapy for patients with multiple risk factors. Specifically, under the "Indications and Usage" section of the Label, Pfizer states, "Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol only when the response to diet and other nonpharmacological measures has been inadequate." See Lipitor Label at 12.

59. The Label further states, "Before instituting therapy with atorvastatin, an attempt should be made to control hypercholesterolemia with appropriate diet, exercise, and weight reduction in obese patients, and to treat other underlying medical problems."

60. Finally, the Lipitor Label permits the use of the drug in persons with multiple risk factors who have a less than 10% chance of developing CHD within 10-years only if the patient's LDL is greater than or equal to 160 mg/dL.

61. The following chart, which is included in Lipitor's Label (Label at 12), clearly illustrates that Lipitor should be prescribed in accordance with the ATP III guidelines:

**TABLE 6. NCEP Treatment Guidelines: LDL-C Goals and Cutpoints for Therapeutic Lifestyle Changes and Drug Therapy in Different Risk Categories**

Risk Category	LDL-C Goal (mg/dL)	LDL Level at Which to Initiate Therapeutic Lifestyle Changes (mg/dL)	LDL Level at Which to Consider Drug Therapy (mg/dL)
CHD <sup>a</sup> or CHD risk equivalents (10-year risk >20%)	<100	≥100	≥130 (100-129: drug optional) <sup>b</sup>
2+ Risk Factors (10-year risk ≤20%)	<130	≥130	10-year risk 10%-20%: ≥130 10-year risk <10%: ≥160
0-1 Risk factor <sup>c</sup>	<160	≥160	≥190 (160-189: LDL-lowering drug optional)

<sup>a</sup> CHD, coronary heart disease

<sup>b</sup> Some authorities recommend use of LDL-lowering drugs in this category if an LDL-C level of < 100 mg/dL cannot be achieved by therapeutic lifestyle changes. Others prefer use of drugs that primarily modify triglycerides and HDL-C, e.g., nicotinic acid or fibrate. Clinical judgement also may call for deferring drug therapy in this subcategory.

<sup>c</sup> Almost all people with 0-1 risk factor have 10-year risk <10%; thus, 10-year risk assessment in people with 0-1 risk factor is not necessary.

62. Since the ATP III guidelines form the basis for Lipitor's prescribing information, promoting Lipitor for patients who do not fall into the ATP III guidelines for drug therapy is illegal, off-label marketing.

63. Despite the language on Lipitor's Label incorporating the ATP III recommendations, as explained in detail below, Pfizer immorally and illegally launched a marketing campaign that minimized and ignored the need for TLC and stated that Lipitor should be prescribed for a group of people for whom TLC is the only recommended treatment. Specifically, Pfizer has misled doctors and patients by illegally promoting Lipitor for use by patients with multiple risk factors where their LDL is greater than 130 mg/dL regardless of their 10-year risk of developing CHD.

64. By improperly expanding Lipitor's use to patients with LDL levels less than 160 mg/dL who face less than a 10% chance of developing CHD within 10 years, Pfizer has increased its potential market for Lipitor by billions of dollars annually.

65. Thus, Pfizer's scheme, while profitable to the Company, caused Lipitor to be prescribed to persons for whom the drug is not medically necessary and not indicated for use on Lipitor's FDA-approved label. Accordingly, the Company has illegally cost third-party payors billions of dollars as they have unwittingly paid for Lipitor's off-label use.

#### **E. Pfizer's Scheme Defrauds Medicare And Medicaid**

66. Pfizer's marketing of Lipitor for off-label uses also illegally caused Medicare, Medicaid, and other government programs to pay for off-label uses of Lipitor in violation of applicable payment guidelines.

67. Medicare is a national health insurance program that provides health insurance to people age 65 or older, people entitled to Social Security disability payments for 2 years or more, and people with end-stage renal disease, regardless of income. The program was enacted July 30, 1965, as Title XVIII, Health Insurance for the Aged of the Social Security Act, and became effective on July 1, 1966. Medicare is administered by the federal government. The Medicare Prescription Drug, Improvement, And Modernization Act Of 2003, Pub. L. No. 108-173 (2003), recently added a prescription drug benefit to Medicare.

68. Medicaid is an entitlement program jointly funded by the state and federal government that pays medical costs for the poor and medically needy.

69. Under federal law, the Medicaid program cannot cover the cost of prescription drugs unless the drug is identified as a "covered outpatient drug[]." 42 U.S.C. § 1396b(i)(10). The definition of covered outpatient drugs excludes any drug not used for a "medically accepted indication." 42 U.S.C. § 1396r-8(k)(2)-(3) ("[A covered outpatient drug] does not include any

such . . . drug or biological used for a medical indication which is not a medically accepted indication”). A “medically accepted indication” in turn is defined as a “use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 301 *et seq.*]” or a use which is “supported by one or more citations included or approved for inclusion in any of the compendia” listed in the statute. *See* 42 U.S.C. § 1396r-8(k)(6). *See also* 42 U.S.C. § 1396r-8(g)(1)(B)(i) (identifying compendia as consisting of: American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information; and the DRUGDEX Information System). A drug’s label generally only contains information about uses approved by the FDA. Drugs are only approved for use by the FDA where a manufacturer demonstrates that the drug is “safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling.” 21 U.S.C. § 355(d).

70. Accordingly, Medicaid cannot legally reimburse the cost of off-label drug uses that are not specifically identified in a drug compendium.

71. Neither Lipitor’s Label nor the drug compendia identified in the Medicaid statute permit the use of statin drug therapy when a patient’s LDL is less than 160 mg/dL when they face less than a 10% chance of developing CHD within 10-years. Accordingly, Lipitor’s use in these patients cannot be reimbursed by Medicaid under prevailing Medicaid payment rules.

72. Similarly, Medicare’s New Prescription drug benefit program defines covered drugs in the same manner as Medicaid. *See* Pub. L. No. 108-173 Sec. 1860D-2(e) (defining covered drug to include “a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), A(ii), or A(iii) of section 1927 k(2) [42 U.S.C. § 1396r-8(k)(2) (defining covered outpatient drug to be limited to approved uses or uses described in a

compendia)]).” Therefore, Medicare cannot legally pay for unnecessary, off-label prescriptions of Lipitor.

73. However, as a consequence of Pfizer’s scheme, Medicare and Medicaid paid billions of dollars to cover the off-label and medically unnecessary use of Lipitor.

**F. Pfizer Defrauds Third-Party Payors**

74. Third-party payors use formularies to determine what drugs to cover for beneficiaries. Formularies are lists of drugs that third-party payors will pay for. The decision to include a drug on a formulary is based on whether a drug is a cost-effective treatment for a particular illness. Generally, formularies create tiers of drugs to incentivize patients to choose certain drugs over more expensive alternatives. For example, patients will generally incur the lowest out of pocket expense for generic drugs or brand drugs that a third-party payor deems particularly cost-effective. However, patients will have to pay a higher out of pocket expense and may have to pay the entire cost of a drug that a third-party payor deems is not a cost-effective treatment.

75. Third-party payors will also place certain drugs on formularies but take additional steps to ensure that the drugs are used in a cost-effective manner. By way of example, some third-party payors require a patient’s physician to call the third-party payor and certify that the patient meets certain clinical criteria before paying for high-risk drugs.

76. Not knowing that Pfizer was engaged in a massive fraudulent scheme to cause the over-prescription of Lipitor, Plaintiffs did not take the necessary steps to ensure the drug was not being over-prescribed.

77. Specifically, Pfizer exploited the fact that third-party payors were unaware of Pfizer’s illegal marketing scheme, did not realize the potential for over-prescription caused by

Pfizer's actions, and therefore did not take precautionary measures reserved for drugs with a danger of being used in medically unnecessary ways.

78. Pfizer's effort to be included in formularies was very successful. Sometime in December 2002, the Company distributed "The Lipitor Healthcare Cluster Playbook" ("Healthcare Playbook") to sales representatives. The Healthcare Playbook, which forbids copying, detailing or distributing, was intended for use by Pfizer's Health Care Cluster, a group of clinical and non-clinical sales persons responsible for increasing the number of Pfizer's institutional customers, such as large employers and managed care organizations. The Healthcare Playbook touts Pfizer's success, stating: "LIPITOR is now on 90% of formularies and is available to 9 of 10 patient lives in the managed care setting. This outstanding formulary penetration and successful messaging has been integral to the impressive sales growth of LIPITOR in 2002. Congratulations!"

## **V. PFIZER'S SCHEME**

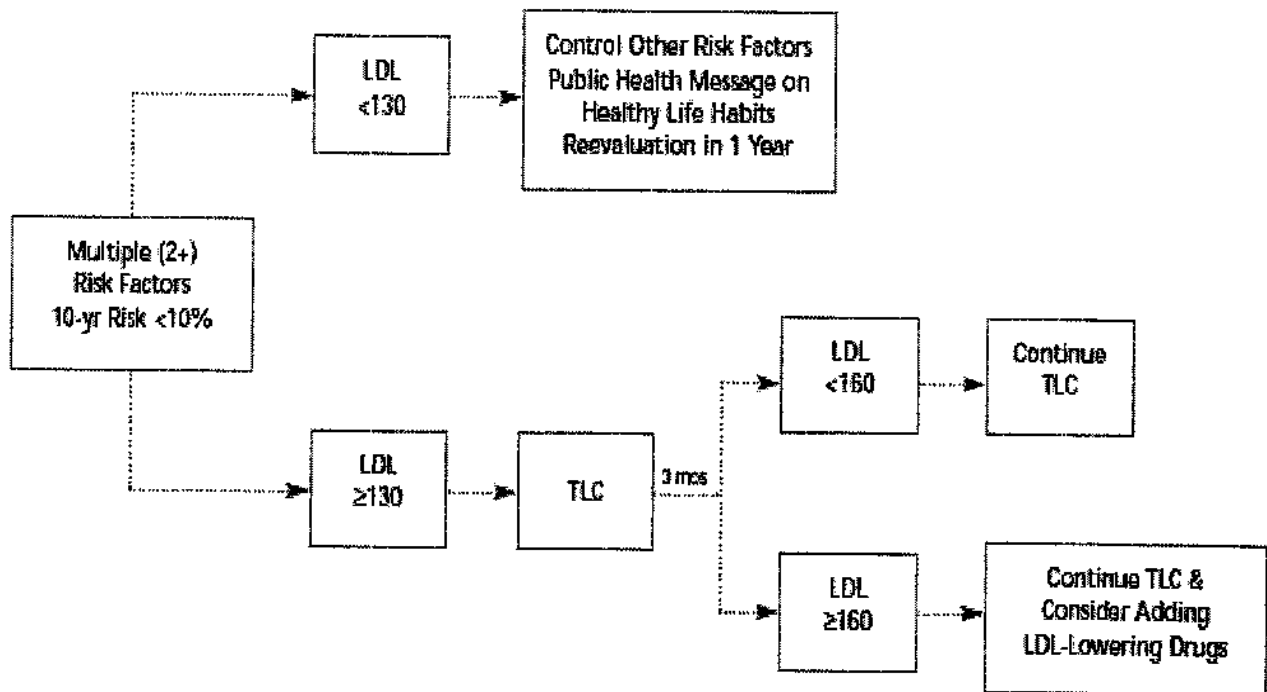
### **A. Pfizer's Scheme Targets A Defined Group Of Persons**

79. Pfizer's scheme focused on expanding the number of patients taking Lipitor beyond what ATP III and the Label recommend. ATP III guidelines recommend that patients with multiple risk factors and less than a 10% risk of developing CHD over the next 10 years may be considered for drug therapy only if their LDL level is 160 ml/dL or higher. For patients with an LDL between 130 ml/dL and 159 ml/dL, the ATP III guidelines recommend only TLC. Nonetheless, Pfizer illegally promotes the drug for use in this patient population.

80. The following chart from the ATP III report illustrates the Panel's recommendations for initiating drug therapy for patients with multiple risk factors but a less than a 10% chance of developing CHD within 10-years:

Figure IV.2-3. Therapeutic approaches to the patient with multiple (2+) risk factors, 10-year risk <10 percent

The LDL cholesterol goal is <130 mg/dL. Drug therapy can be considered if LDL cholesterol is  $\geq 160$  mg/dL after a trial of TLC.



ATP III Report at IV-7.

81. As illustrated in the foregoing chart, the LDL level at which to initiate drug therapy is considerably higher than the LDL goal level of persons with multiple CHD risk factors whose 10-year CHD risk is less than 10%. Pfizer, however, targeted the group of patients with LDL levels between 130 mg/dL and 159 mg/dL with less than a 10% chance of developing CHD within 10-years because there are over 14 million potential Lipitor users in that group.

**B. Pfizer's Illegal Promotion Of Lipitor Targets Pharmacy Benefit Decision Makers, Physicians, And Consumers**

82. Pfizer promoted the off-label use of Lipitor through a nationwide campaign using promotional materials and programs for its core customer segments: pharmacy benefit decision makers, physicians, and consumers.

83. Pfizer's marketing materials include: ATP III training slides for Pfizer employees and external audiences, such as the Physician Speaker's Bureau; computer software programs, internet programs; health fair programs; "leave behind" materials; and visual aids. For all of these target populations, the same false message, contrary to Lipitor's FDA-approved label and ATP III's recommendations was created: ATP III recommends drug therapy for all patients with multiple risk factors regardless of their 10-year risk of CHD if their LDL levels are greater than their LDL "goal" of 130 mg/dL.

84. Pfizer's marketing scheme was carried out despite the Company's knowledge that the ATP III guidelines state that the LDL "goal" is not the LDL level for initiating drug therapy and that the guidelines do not recommend drug therapy for patients with a less than 10% risk of developing CHD within 10 years unless their LDL level is greater than or equal to 160 mg/dL.

85. Pfizer ignored the guidelines and launched a marketing campaign that sought to treat any person not at "goal" with Lipitor. Pfizer omitted, however, statements necessary to correct the false impression Pfizer was deliberately and relentlessly creating, namely, that any person not at "goal" should be treated with Lipitor.

**1. Pfizer Illegally Promotes The Off-Label Use Of Lipitor To Pharmacy Benefit Decision Makers**

86. Pfizer illegally promotes Lipitor to Pharmacy Benefit Decision Makers ("PBDMs"), persons who help third-party payors design their pharmacy benefit plans. PBDMs

often assist third-party payors develop formularies, which entails making choices about which drugs to cover and how much third-party payors will reimburse for certain drugs.

87. In presentations to PBDMs, Pfizer illegally promoted off-label use of Lipitor by stating that all patients with multiple risk factors of CHD should be treated with Lipitor if they are unable to reach their cholesterol goal. In reality, ATP III, incorporated by reference on the Label, only recommends that for persons with multiple risk factors of CHD but less than a 10% chance of developing CHD within 10-years, Lipitor should only be prescribed if the patient's LDL is greater than or equal to 160 mg/dL. This is well above their goal of 130 mg/dL and thus Pfizer seeks to have Lipitor prescribed for millions of persons with LDL between 130 mg/dL and 159 mg/dL, even though drug therapy for these patients is unnecessary, expensive and exposes patients to medically unnecessary risks.

88. Specifically, one of Pfizer's programs aimed at PBDMs, "Cholesterol Management in the Work Place: Information for Benefit Decision Makers," stresses "the cost of lost productivity due to uncontrolled cholesterol" in the workplace. As part of the marketing program, Pfizer representatives use a compact disc containing a slide presentation and also a "leave behind" brochure. The compact disc includes a series of slides grouped into the following categories: (1) "The Prevalence and Cost of High Cholesterol;" (2) "The Treatment Gap;" (3) "Therapeutic Options;" and (4) "Workplace Initiatives."

89. One slide on the compact disc in the "Therapeutic Options" section entitled "When to consider drug therapy in the management of high cholesterol" fraudulently mischaracterizes the ATP III guidelines. At the bottom of the slide, in large font for emphasis, are instructions for the Pfizer marketing employees who give the presentation that states: "For individuals with <20% risk, drug therapy may be considered after lifestyle changes alone have

failed to achieve LDL goal.” This recommendation is contradicted by the ATP III guidelines, which do not recommend drug treatment for those patients with multiple risk factors who face less than a 10% chance of developing CHD within 10 years unless their LDL is equal to or greater than 160 mg/dL.

90. Pfizer’s fraudulent statements to PBDMs were incorporated into more than one presentation. As part of a separate presentation to PBDMs entitled “Lipid lowering and prevention of coronary heart disease: A managed care perspective,” Pfizer included similar fraudulent statements in a leave-behind brochure. The brochure contains a chart showing LDL goals accompanied by the following statement: “Lowering lipid levels can help prevent CHD.” The brochure conveys the misleading impression that Lipitor should be used by all patients who are unable to reach their cholesterol goal when in reality the ATP III guidelines recommend that a substantial number of people only begin Lipitor treatment when well (30 mg/dL or more LDL points) above goal.

91. Pfizer also illegally promoted the off-label use of Lipitor through a slide presentation entitled “Lipid Lowering Slide Kit” that was included on two compact discs as part of Pfizer’s “Lipid Lowering and Prevention of Coronary Heart Disease: A Managed Care Perspective” marketing program. The first CD contains a slide entitled “The first step in reducing LDL-C: Therapeutic Life Changes (TLC).” The slide states that if LDL goal is not achieved through TLC, drug therapy should be considered.” In this statement, Pfizer is improperly promoting an off-label use of Lipitor as the ATP III guidelines recommend that many patients consider drug therapy when their LDL level is well above their ultimate goal.

92. Unaware of Pfizer’s scheme, and deceived by Pfizer’s failure to disclose that Pfizer was advocating the medically and economically unjustified “treating to goal” approach,

PBDMs included Lipitor on their drug formularies, thereby increasing the market for Lipitor. PBDMs, and third party payors, such as the Plaintiffs, reasonably relied on the understanding that Pfizer, as its website declares, was abiding by the law and not illegally promoting off-label uses.

## **2. Pfizer Illegally Induces Physicians To Prescribe Lipitor For Off-Label Uses**

93. Pfizer's promotion of Lipitor's off-label use was also targeted at physicians. Pfizer used outreach programs, speaker events, sales calls, and computer software to mislead doctors about the FDA-approved uses of Lipitor. For example, Pfizer's Lipitor 2002 US Operating Plan ("Operating Plan") laid out the Company's illegal scheme. According to that document, Pfizer's primary concern when communicating to doctors about Lipitor was to "Emphasize New LIPITOR 'Get to Goal' Messages."

94. Pfizer's "Get to Goal Message" entailed recommending Lipitor for use by patients above goal, but for whom ATP III did not recommend drug treatment. When Pfizer communicated information about Lipitor to physicians, Pfizer fraudulently told them that ATP III recommended that they should prescribe Lipitor to all patients who could not reach their LDL goal. For example, Pfizer routinely plied doctors with gift cards to stores such as Target, accompanied by exhortations to "get your patients' LDL levels to their target" via Lipitor use without regard to the ATP III guidelines.

95. As part of their marketing campaign, Pfizer prepared a standard slide presentation that fraudulently mischaracterized the ATP III guidelines. These slides were designed and approved by Pfizer's Corporate Lipitor Disease Management Team and used by Pfizer for different purposes including: (1) to train Pfizer's clinical and non-clinical personnel and paid physician consultants; (2) to "educate" Pfizer's customers; and (3) to serve as the basis for

Pfizer's presentation given to doctors encouraging them to prescribe Lipitor. The slide presentation enables Pfizer to uniformly promote the off-label use of Lipitor on a massive scale.

96. One of the misleading slide presentations is entitled "The Lipid Slide Library Volume 2: National Cholesterol Educational Program Adult Treatment Panel III Guidelines." The slide presentation is accompanied by speaker notes. The speaker notes to slide 1 state: "This program highlights the new NCEP ATP III guidelines for your clinical practice, as well as information on lipid-lowering therapy with atorvastatin calcium [Lipitor]." However, the slides are intended to promote the off-label use of Lipitor by falsely stating that ATP III recommends that all patients who were not able to reach LDL goal with TLC should begin Lipitor. Specifically, the commentary for slide 14 falsely states: "[L]ipid-lowering drug therapy should be considered for patients not at LDL goal after 3 months of therapeutic lifestyle changes." The slide presentation never states that for certain patients, Lipitor therapy should not be initiated unless the patient's LDL is greater than or equal to 160 mg/dL, well above their goal of 130 mg/dL.

97. This slide presentation was repeated to doctors around the country numerous times. For example, Pfizer's Local Marketing Team in Atlanta created the Cardiovascular Leadership Council ("CLC") in 2002 to further the reach of Pfizer's illegal marketing campaign. The CLC was designed to influence "thought leaders and targeted physicians" with Pfizer's misleading message. As part of the program, Pfizer sponsored promotional dinners and CME courses for both cardiologists and primary care physicians. The program was intended to increase market share of Lipitor "by educating physicians in the marketplace about the importance of treating to goal." As part of "educating" physicians, the CLC provided speakers to their events with the misleading slide presentation promoting Lipitor's off-label use.

98. Additionally, Pfizer also illegally promoted the off-label use of Lipitor to rural physicians through Pfizer's program entitled "Pfizer Facilitating the Advancement of Rural Medicine" or "PFARM." As part of PFARM, Pfizer sent speakers to give misleading presentations to rural doctors about the use of drug therapy to control LDL. PFARM's purported objective was to "provide rural practitioners with solutions to managing patients with high-risk and potentially costly conditions (hypertension and hypercholesterolemia)." Again, Pfizer gave these speakers slides that deceptively gave the impression that all patients should be treated with Lipitor if they are unable to get to their LDL goal. In reality, ATP III only recommends that a fraction of these patients consider using Lipitor if they are not at goal; for patients with multiple risk factors of CHD and less than a 10% chance of developing CHD within 10 years, ATP III does not recommend Lipitor treatment unless their LDL is greater than or equal to 160 mg/dL.

99. For example, slide 18 of the PFARM presentation presents ATP III's LDL goals without stating that ATP III sometimes recommends that physicians initiate Lipitor treatment at levels higher than goal. Both "moderate risk" patients (patients with multiple risk factors and less than a 10% chance of developing CHD within 10-years) and "moderately high risk" patients (patients with multiple risk factors and a 10% to 20% chance of developing CHD within 10-years) were confusingly grouped together as having an LDL goal of 130 mg/dL. ATP III guidelines, however, clearly recommend that moderate risk patients consider drug therapy only if their LDL cholesterol is greater than or equal to 160 mg/dL.

100. In its first national training meeting of 2002 for Pfizer's pharmaceutical sales representatives, entitled POA 1 (Plan of Action), Pfizer introduced a program called "POA Strategic Selling Guide Featuring Action Selling." It encourages Pfizer marketers to adopt three strategies: (1) encourage physicians to identify new patients for treatment; (2) illustrate safety

and efficacy; and (3) dominate share of voice with detail frequency and strategic sample distribution. At POA 1, another message Pfizer wanted its marketers to convey to doctors was that they have the “[p]ower to help the majority of patients reach their goal.”

101. Pfizer’s sales representatives were specifically trained to push Pfizer’s “get to goal” message without regard to whether drug therapy was recommended under the ATP III guidelines. In fact, beginning in at least 2003 sales people were trained to convince doctors to get their patients’ LDL levels down via Lipitor to 100 mg/dL or below, regardless of the patient’s risk factors, and to be “more aggressive” than the ATP III guidelines.

102. The fact that therapeutic lifestyle changes were the only recommended therapy under ATP III for certain moderate risk patients was ignored by Pfizer’s sales representatives and the company’s employees hired to train them.

103. Pfizer also used computer software to perpetuate its scheme. Specifically, a software program entitled “Lipid Goal Manager” was distributed in the Healthcare Playbook (*see supra* at ¶77). The software was intended to be used by marketers to help physicians “integrat[e] NCEP ATP III guidelines into routine practices.” The software enabled doctors to input certain variables about a patient (age, sex, and LDL cholesterol level) and then analyze whether the patient was at their ATP III goal. However, as illustrated below, the software illegally promoted the off-label use of Lipitor.

104. For example, if the following patient information is entered into the software program - 43 year-old female with LDL-C of 135 mg/dL and three risk factors - the following report is generated:

RISK ASSESSMENT AND LDL GOAL

NCEP Risk Category: 2 or more risk factors (10-year risk <20%)

NCEP LDL-C level: <130 mg/dL

Patient's LDL-C level: 135 mg/dL

Patient's 10-year risk: 4 percent

TO MEET NCEP GOAL LDL-C, LEVELS SHOULD BE  
LOWERED BY 6 mg/dL OR MORE (4.44 percent)

105. Similarly, if the following patient information is entered into the database - 43 year-old male with LDL-C of 131 mg/dL and two risk factors - the following report is generated:

RISK ASSESSMENT AND LDL GOAL

NCEP Risk Category: 2 or more risk factors (10-year risk <20%)

NCEP LDL-C level: <130 mg/dL

Patient's LDL-C level: 131 mg/dL

Patient's 10-year risk: 8 percent

TO MEET NCEP GOAL LDL-C, LEVELS SHOULD BE  
LOWERED BY 2 mg/dL OR MORE (1.53 percent)

106. In both cases, Pfizer programmed the software to generate a deceptive letter that the physician could send to his patients. For the two patients above, the software generated a letter that stated: "[A] low fat diet, proper exercise, and medication will help lower your cholesterol levels, especially your LDL-cholesterol (bad cholesterol). . . ." (emphasis added).

107. However, based on ATP III guidelines, these patients should not be considered for drug therapy because both patients' risk of developing CHD within 10 years was less than 10% and their LDL was less than 160 mg/dL. Therefore, creating software that falsely stated that medication will help lower their LDL, when ATP III only recommends TLC for these

patients, was another facet of Pfizer's scheme to increase the patient population of Lipitor through the use of deception.

108. Furthermore, the software also generates a report that doctors can give to patients entitled: "What is your cholesterol goal?" It shows three risk categories and three goals for "bad" LDL. The second category is "two or more risk factors and a 10-year coronary heart disease risk of <20%" and the LDL goal for the category is "below 130 [mg/dL]." The report, however, neglects to state that a significant percentage of these patients, those with less than a 10% chance of developing CHD, should not begin drug therapy unless their LDL cholesterol is greater than or equal to 160 mg/dL.

109. Pfizer also used its website to illegally promote the off-label use of Lipitor to physicians. Specifically, the Company stated that ATP III updated the existing guidelines and reduced LDL goal from 130 mg/dL to an optional goal of 100 mg/dL for patients with two risk factors of CHD. However, that statement is false. The ATP III 2004 updates only recommended an optional goal of 100 mg/dL for patients with multiple risk factors and a 10% to 20% chance of developing CHD in the next 10 years. For patients with two or more risk factors of CHD with less than a 10% chance of developing CHD in the next 10 years, the 2004 ATP III updates left the LDL goal of 130 mg/dL unchanged.

### **3. Pfizer Illegally Promotes Lipitor's Off-Label Use To Consumers**

110. To target Hispanic consumers directly with the Company's illegal marketing scheme, Pfizer implemented a number of direct to consumer ("DTC") marketing programs. One program, the Sana La Rana program, targeted "low health literacy" Spanish speaking populations. It utilized print, radio, and television advertising and also had a website. The website sought to promote the off-label use of Lipitor by stating that people with multiple risk factors of CHD have an LDL goal of 130 mg/dL while failing to mention that those with a less

than a 10% risk of CHD should not start Lipitor unless their LDL is greater than or equal to 160 mg/dL.

111. The Sana La Rana project had a large impact on consumers. The campaign ran from June 2003 to December 2003. In that time, Pfizer distributed 400,000 patient education brochures and hosted 282 community charlas (chats) that reached 4,300 people in Houston and Miami. Its website received 13,000 hits and it received 5,300 phone calls.

112. Another marketing campaign directed at consumers, the "Boston Heart Party," which describes itself as "Boston's leading cardiovascular disease awareness campaign for women," similarly misrepresents the ATP III guidelines. An email message from Valerie Sullivan, Pfizer's Director of Marketing for the Boston Local Market Team, stated: "[T]he educational piece of [the Boston Heart Party] would highlight the importance of treating aggressively to goal, especially in light of the new ATP III goals." Like much of Pfizer's marketing campaign, it did not inform consumers that for a large number of patients, ATP III does not recommend drug therapy unless the person is at least 30 mg/dL points above their LDL goal.

**C. Pfizer's Scheme To Promote The Off-Label Use Of Lipitor Downplays The Significance Of TLC**

113. In order to illegally increase Lipitor's off-label use, Pfizer also downplayed the importance of TLC in controlling LDL levels. Specifically, consumers who register at Lipitor.com are emailed a message stating "Don't worry, a high cholesterol number may not be your fault. But it's probably time for some extra help." The message also contains a link stating: "Get up to \$10 off a Lipitor prescription. It's a great way to get started." Pfizer's email deceptively omits that under ATP III guidelines, diet and exercise should be tried before starting Lipitor.

114. Pfizer also sought to downplay the importance of TLC in its DTC advertising. Specifically, on page 55 of the Operating Plan (dealing with DTC advertising), Pfizer outlines its marketing strategies which seek to saturate consumers with messages such as “High cholesterol is not your fault and your doctor can help you” and “Lipitor is the most effective treatment.” These statements are misleading because they downplay the importance that TLC can make in reducing cholesterol and also run afoul of the ATP III’s guidelines that recommend initially using TLC to reach LDL goals.

**D. Pfizer’s Illegal Promotion Of Lipitor’s Off-Label Use Is Orchestrated At The Highest Levels Of The Company And Is Crucial To The Company’s Business Plan**

115. Pfizer’s illegal scheme to promote the off-label use of Lipitor was orchestrated at the highest levels of the Company and was critical to its business model.

116. In communications to investors, Pfizer touted the potential “market” for Lipitor and the prospects for Lipitor’s success. However, Pfizer’s touting of Lipitor’s potential growth failed to inform investors that this explosive growth could only be achieved if Lipitor was prescribed for off-label, non-compendium use for millions who did not need it and for whom ATP III only recommended TLC. In its representations to investors, Pfizer suggested that all persons not at their LDL goal could benefit from Lipitor. According ATP III guidelines, this simply was not true.

117. Specifically, Pfizer’s Second-Quarter 2004 Performance Report, which was filed with the SEC on Form 8-K on July 21, 2004, blatantly promotes Lipitor’s off-label use as a business opportunity for Pfizer. In the performance report, Karen Katen – currently Vice Chairman of Pfizer, President of Pfizer’s Human Health Division, and a member of the Company’s Executive Committee – states: “[F]resh evidence on statins, and the new U.S.

guidelines it has driven, portend more growth potential for Lipitor. Landmark studies such as ASCOT-LLA, CARDS, PROVE-IT, REVERSAL, and Alliance have demonstrated the dramatic health benefits of ever-lower cholesterol, as effected by Lipitor, benefits such as reduced strokes, heart attacks, and the need for invasive procedures. The medical community's growing recognition of this value means in the U.S. alone, 18.5 million new patients could benefit from lipid-lowering therapy, elevating the number of Americans Lipitor could help to about 79 million, or 40 percent of all adults. This new evidence on Lipitor underscores the opportunities for even our major products to help substantially more patients.” (emphasis added).

118. Pfizer never cites a source for its estimate that 79 million people could benefit from Lipitor. Moreover, Pfizer's estimated 79 million potential Lipitor users is wholly inconsistent with NCEP estimates. As stated above, NCEP has estimated that approximately 37 million people are eligible for statin drug therapy under ATP III. Even considering that the 2004 updates to ATP III, which have not yet been incorporated in Lipitor's FDA-approved label, expanded the potential patient population for Lipitor, Pfizer's statement that 79 million persons could benefit from Lipitor is blatantly wrong. See John Fauber, *Doubts Raised Over Drugs For Cholesterol*, MILWAUKEE JOURNAL SENTINEL, Mar. 27, 2004 (statins are recommended for 36 million Americans). See also Bennett M. Paone, Managing dyslipidemias: update on guidelines and pharmacotherapy, available at [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=retrieve&db=pubmed&dopt=Abstract&list\\_uids=12296547&query\\_hl=2&itool=pubmed\\_docsum](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=retrieve&db=pubmed&dopt=Abstract&list_uids=12296547&query_hl=2&itool=pubmed_docsum) (accessed Mar. 19, 2006) (“Based on ATP III, 65 million Americans need therapeutic lifestyle changes, 36.5 million of whom require drug therapy.”). Despite the fact that only 36.5 million Americans are eligible for statin therapy, Pfizer constructed a massive fraudulent scheme to

target 79 million Americans (or 40% of all adults in the United States) to take Lipitor, even though for many of those people Lipitor was a dangerous and unnecessary drug.

**E. Pfizer Improperly Utilizes Third-Parties To Promote Its Fraudulent Scheme**

119. Pfizer paid outside marketing/sales firms, physician consultants, and other consultants who were not employees of Pfizer to fraudulently promote the off-label use of Lipitor. Pfizer also funded third-party entities -- including Emerging Science in Lipid Management ("ESLM") and the National Lipid Education Council ("NLEC") (NLEC changed its name in 2006 to the Committee on Cardiovascular and Metabolic Disease) -- that offered CME courses to doctors and published articles promoting Lipitor's off-label use. ESLM and NLEC both purport to educate physicians about the treatment of high cholesterol. However, both organizations are fully funded by Pfizer and play an important role in the illegal off-label marketing of Lipitor. Pfizer's use and coordination of third-party entities to promote its fraudulent scheme is manifested in its Operating Plan. Page 32 of the Operating Plan is titled "Medical Education Platform Supports the New Positioning." In that section, Pfizer states that it plans to use ESLM and NLEC in its scheme to market Lipitor. As further detailed below, both of these entities, fully funded by Pfizer, deceptively promote off-label use of Lipitor.

**1. Pfizer Used The National Lipid Education Council To Further Its Scheme To Promote The Off-Label Use Of Lipitor**

120. Pfizer is the sole source of funding for NLEC. Pfizer channels money to the organization through an unrestricted educational grant to Thomson Professional Postgraduate Services ("PPS"), a division of Thomson Corporation's healthcare group. PPS "develops medical educational activities designed to meet the needs of practicing physicians. PPS, working with medical leaders, designs and implements effective programs to meet specific educational objectives."

121. PPS sponsors NLEC, giving the entity the illusion that it is independent of Pfizer's influence.

122. According to its mission statement, NLEC began in 1996 as the Lipid Management in Clinical Practice program. Its purported goal is "focused on educating physicians and other healthcare professionals about the rationale for aggressive cholesterol-lowering therapy, specifically to achieve LDL-C targets, in order to prevent or manage adverse cardiovascular events." Furthermore, NLEC claims: "Through multifaceted educational activities — including national and regional symposia as well as a variety of print, audio, and visual media — the NLEC strives to reach healthcare professionals nationwide to effect better health outcomes for patients." In reality, NLEC repeatedly conflated on and off-label uses of Lipitor in an attempt to confuse doctors and increase the number of Lipitor users.

123. CME courses provided by NLEC repeatedly distorted the line between on and off-label use of Lipitor. These CME courses purportedly provide educational material to practicing physicians and are often presented at high-end restaurants, through newsletters, and the internet. One often used technique is to present case studies to physicians of patients who were successfully treated with Lipitor. NLEC's CMEs contain an overall disclaimer stating that "discussions are present of off-label, non-FDA approved uses of certain therapies." Furthermore, in the introduction to online "Virtual Case Studies," the NLEC website states: "[S]ome treatment[s] outlined in these sections in these cases may not adhere to National Cholesterol Educational Treatment Panel III (ATP III) guidelines." However, it is wholly unclear from the CME materials what is an approved use and what is not an approved use of the drug, and participants in these programs are not informed which are and which are not approved uses.

124. For example, a CME case study on NLEC's website promotes the use of a statin in patients with LDL below 160 mg/dL, multiple risk factors, and a 10-year CHD risk of less than 10%. Significantly, at no point does NLEC mention that ATP III guidelines do not recommend treatment for this patient. In fact, the patient in the case study is alternately described as "moderately high risk," "relatively high risk," and at "high risk." According to ATP III guidelines, however, this patient would only need drug therapy if his LDL was greater than or equal to 160 mg/dL. This case is also deceptive because it states ATP III goals without stating cholesterol levels when physicians may consider initiating drug therapy. But NLEC was well aware of the ATP III guidelines, knew that drug treatment is not indicated for patients with the characteristics identified, but nonetheless promoted the use of statins by such patients in order to continue to receive funding from Pfizer.

125. Pfizer influences NLEC's operations by retaining NLEC's leaders as consultants and/or providing research/grant monies to NLEC's directors. Specifically, Dr. Antonio Gotto, NLEC's chairman, has been retained by Pfizer as a consultant. Additionally, virtually every member of NLEC's Steering Committee has served as a Pfizer consultant and/or has received funding from Pfizer. The following members of NLEC's steering committee also have financial ties to Pfizer: Dr. Peter Ganz (Pfizer consultant); Dr. Steven Haffner (Pfizer consultant and member of Pfizer's speaker bureau); Dr. Ronald Krauss (Pfizer consultant, member of Pfizer's speaker bureau, and Pfizer grantee); Dr. John LaRosa (advisor/consultant to Pfizer); Dr. Peter Libby (Pfizer consultant, recipient of grants and research support from Pfizer, and chairman of the steering committee for the Treating to New Targets Study, a Pfizer/Parke-Davis study that focused on the benefits of atorvastatin in patients with CHD); and Dr. Thomas Pearson (Pfizer consultant and member of the data safety and monitoring board of the PROVE-IT Trial).

126. Pfizer's ties to Thomson Corp. ("Thomson") extend well beyond its relationship with PPS. Thomson relies on Pfizer for purchasing several products from the company.

127. One such product, Lectora, is touted by Thomson as being used by Pfizer to unify the Company's "enterprise-wide learning programs." Thomson also touts Pfizer's use of its "MDC" program, which provides IP management services on Thomson Scientific's website.

128. Pfizer also partnered with Thomson Prometric (a division of Thomson), which promotes itself as the global leader in technology-enabled testing and assessment services. A March 30, 2004, press release from Thomson Prometric states: "Thomson Prometric and Pfizer, Inc. have collaborated since 2000. Pfizer discovers, develops, manufactures and markets leading prescription medicines for humans and animals, including some of the world's best-known consumer brands. In 2003, they chose to continue their agreement with Thomson Prometric to take advantage of Thomson Prometric psychometric services."

129. Accordingly, Pfizer and Thomson are associated on several levels beyond Pfizer's reliance on PPS to help it fund NLEC.

## **2. Pfizer Used The Emerging Science Of Lipid Management To Further Its Scheme To Promote The Off-Label Use Of Lipitor**

130. ESLM was mentioned in Pfizer's Operating Plan as a key component to help the Company boost Lipitor's sales. According to ESLM's website, the organization is funded by an unrestricted grant from Pfizer. Moreover, ESLM shares directors with NLEC – Dr. Gotto (NLEC chairman) and Dr. Libby (NLEC steering committee member) both serve as national faculty co-chairs for ESLM. This cross-pollination of supposedly independent entities with the same individuals and a common source of funding – Pfizer – ensured that Pfizer's "get to goal" marketing mantra was proclaimed loudly and clearly.

131. Convergent Health Solutions, LLC (“Convergent Health Solutions”) and the Dannemiller Memorial Educational Foundation sponsor ESLM, giving the program the illusion that it is independent from Pfizer’s influence. Convergent Health Solution is a full service medical education organization that develops CME courses. *See* Convergent Health Solutions Website, <http://www.convergent-health.com/about.asp?p=1> (last visited July 6, 2006). The Dannemiller Memorial Educational Foundation “work[s] closely with education and communications companies to design, develop and present educational programs in almost every media to meet the needs of physicians and other healthcare professionals.” Dannemiller Memorial Educational Foundation Website, [http://www.dannemiller.com/about\\_dannemiller.cfm](http://www.dannemiller.com/about_dannemiller.cfm) (last visited July 6, 2006). Both these organizations helped Pfizer create ESLM by sponsoring the CME program, which the Company used to market Lipitor.

132. ESLM’s website states: “Launched in the spring of 2001, the Emerging Science of Lipid Management (ESLM) initiative is a strategy for educating physicians across the country about fundamental changes in the scientific and clinical understanding of atherosclerosis and heart disease.”

133. Under the Learning Objectives section of ESLM’s website the organization states:

The purpose of the Emerging Science of Lipid Management CME initiative is to increase recognition of dyslipidemias, highlight the importance of cardiovascular risk assessment, and foster appropriate early and aggressive treatment and follow-up of lipid abnormalities.

At the conclusion of an ESLM educational activity, the participant should be able to:

- Identify appropriate candidates for aggressive lipid management
- Recognize the benefits of multifactorial lipid therapy in patients, including underserved populations, across the spectrum of cardiovascular disease risk

- Understand the cardiovascular consequences of metabolic dysfunction, including insulin-resistance syndromes, obesity, and diabetes
- Adopt effective strategies for managing dyslipidemia [(abnormal lipid levels)] in everyday clinical practice

134. ESLM's website also notes: "ESLM will directly reach thousands of cardiologists, cardiology fellows, and other physicians through a series of innovative CME-accredited educational activities. In addition, 18,000 cardiologists and 60,000 internal medicine physicians will receive the quarterly *Lipid Letter*, a 12 page newsletter that disseminates the latest findings on managing dyslipidemia." The *Lipid Letter* is co-chaired by Dr. Gotto and Dr. Libby.

135. However, ESLM uses "educational programs" to promote Lipitor's off-label use. In the September 2005 volume of the *Lipid Letter* Dr. Gotto and Dr. Libby wrote an article titled "Statin Safety: Weighing the Evidence," which stated, contrary to ATP III guidelines, that "reducing serum LDL-L from any baseline level lowered risk further in high-risk patients." (emphasis in original).

136. In 2004, an invitation was mailed to physicians inviting participation in ESLM's national program providing free CME credit entitled "New Paradigms in Cardiovascular Risk Reduction: A CME Teleconference." ESLM's invitation stated: "At the conclusion of this activity, participants should be able to apply NCEP guidelines and other data to management of patients who have, or who are at risk of coronary heart disease." However, during the presentation, participants are given little guidance of where discussion of NCEP guidelines end and where discussion of off-label use of the drug begin. A carefully worded disclaimer states: "Off-Label Discussion: In the event that a speaker discusses a product that is either not approved or the product is investigational, the speaker will disclose this information to the audience at the

time of the presentation.” However, it is important to note that this disclaimer does not address disclosures concerning Lipitor’s off-label uses.

137. ESLM also provided paid consultants from Pfizer a platform to promote Lipitor’s off-label use. For example, in a CME titled “A 65-Year-Old African American Man with Low HDL-C,” Dr. Matthew Sorrentino, who received funding from Pfizer and has given lectures sponsored by Pfizer, presents a case study where a 65-year old African American male with known CHD and an LDL of 87 mg/dL was given statin therapy for three months. The CME’s first key point states, “Therapeutic lifestyle changes should be the initial approach to the treatment of dyslipidemia. *In patients for whom this approach is not adequate, statin therapy can help patients meet their target LDL-C level,* and fibrate or niacin therapy may be effective in raising low HDL-C levels.” (emphasis added). This CME blatantly promotes the off-label use of Lipitor. First, according to the Label, this patient should not have received statin therapy unless his LDL was greater than or equal to 100 mg/dL. Second, contrary to the CME’s key point, according to ATP III guidelines, statin therapy should be administered to patients who are not at their LDL goal after initiating TLC but only if their LDL remains above the number at which ATP III recommends drug treatment.

138. ESLM also provides Pfizer and its paid consultants an outlet to undermine the health concerns expressed over statin use. For example, in the “Patient Education” section of ESLM’s website, the organization posted a paper titled “What You Need to Know About . . . Statins and Other Medications For Preventing a Heart Attack.” The paper, prepared by Dr. Dennis DeSilvey and funded by Pfizer, downplays the risks associated with statin use. Specifically, in responding to the question “[a]re statins safe?” Dr. DeSilvey writes, “The risk of

side effects with statins is very low – only about 1 to 2 chances in 100. Serious side effects are even less common, occurring in about 1 in 1000 patients.” The paper also states:

If you choose not to take cholesterol-regulating medication, there’s a greater chance that your cholesterol levels can damage your blood vessels, which will increase your risk of having a heart attack or stroke. Keep in mind that your chances of developing heart disease are much greater than your risk of having a bad side effect from taking a statin. The evidence from scientific studies clearly shows that the potential benefits of taking a statin far outweigh the potential risks.

139. Although not disclosed in the preceding paper, the June edition of the *Lipid Letter* states, “Dr. DeSilvey reports that he is on the speakers’ bureau for Pfizer Inc.”

### **3. Pfizer Used Independent Consultants To Promote The Off-Label Use Of Lipitor**

140. In addition to using NLEC and ESLM to promote Lipitor’s off-label use, Pfizer also used paid independent consultants to illegally expand the off-label uses of the drug.

141. A CME titled “Statins May Reduce Cardiovascular Risk in Type 2 Diabetes,” released on August 23, 2004, promoted off-label use of Lipitor. As part of the CME, Dr. Helen M. Colhoun stated that “Atorvastatin 10 mg daily is safe and efficacious in reducing the risk of first cardiovascular disease events, including stroke, in patients with type 2 diabetes without high LDL-cholesterol . . . No justification is available for having a particular threshold level of LDL [low-density lipoprotein]-cholesterol as the sole arbiter of which patients with type 2 diabetes should receive statins.” Dr. Colhoun’s comments were based on the Collaborative Atorvastatin Diabetes Study (“CARDS”) published in the Aug. 21 issue of *The Lancet*. CARDS was funded by, *inter alia*, Pfizer UK and Pfizer Inc. Moreover, according to *The Lancet*, Dr. Colhoun served as a consultant to Pfizer and received travel expenses and payments for speaking at meetings from the Company.

142. Pfizer employed a multifaceted and uniform scheme to misrepresent the ATP III guidelines in order to expand the number of persons using Lipitor. This scheme was carried out

without any regard for the safety of people using Lipitor. Pfizer's scheme – which made Lipitor the world's first \$12 billion a year drug – exploited the willingness of third-party payors to pay for on-label uses of Lipitor to promote its off-label sales.

## VI. CLASS ACTION ALLEGATIONS

143. Named Plaintiffs bring this action as a class action pursuant to Fed. R. Civ. P. 23(a), (b)(2), and (b)(3) on behalf of a nationwide class of third-party payors and state medical assistance programs (including, *inter alia*, state Medicaid programs and state employee benefit plans) for all fifty states and the District of Columbia, that paid any part of Lipitor's purchase price for its off-label use ("Nationwide Class"). Named Plaintiffs seek class certification under Fed. R. Civ. P. 23(b)(2) as to declaratory and equitable relief sought herein, and under Fed. R. Civ. P. 23(b)(3) as to the damages sought herein. The Nationwide Class asserts claims under RICO, civil conspiracy, unjust enrichment, and seeks an accounting of Pfizer's gains from the off-label promotion of Lipitor.

144. Plaintiffs Southern Illinois L&E, NECA-IBEW, and Midwestern Teamsters H&W also bring this action on behalf of a sub-class of third-party payors located in Illinois that paid any part of Lipitor's purchase price for its off-label use ("Illinois Statewide Class"). The Illinois Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and under Illinois' Consumer Fraud and Deceptive Business Practices Act, 815 ILL. COMP. STAT. 505/1 *et seq.*

145. Plaintiff Local 863 Fund also brings this action on behalf of a sub-class of third-party payors located in New Jersey that paid any part of Lipitor's purchase price for its off-label use ("New Jersey Statewide Class"). The New Jersey Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and under the New Jersey Consumer Fraud Act ("CFA"), N.J.S.A. §§ 56:8-1 *et seq.*

146. Plaintiff Plumbers & Pipefitters Fund also brings this action on behalf of a sub-class of third-party payors located in Florida that paid any part of Lipitor's purchase price for its off-label use ("Florida Statewide Class"). The Florida Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and under Florida's Deceptive and Unfair Trade Practices Act ("DUTPA"), FLA. STAT. §§ 501.201, *et seq.*

147. Plaintiff CB&T Fund also brings this action on behalf of a sub-class of third-party payors located in Ohio that paid any part of Lipitor's purchase price for its off-label use ("Ohio Statewide Class"). The Ohio Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and under Ohio's Consumer Sales Practices Act, OHIO REV. CODE ANN. §§ 1345.01, *et seq.* ("CSPA").

148. Plaintiff EWBTF also brings this action on behalf of a sub-class of third-party payors located in Indiana that paid any part of Lipitor's purchase price for its off-label use ("Indiana Statewide Class"). The Indiana Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and under Indiana's Deceptive Consumer Sales Act ("DCSA"), Ind. Code §§ 24-5-0.5-1, *et seq.*

149. Plaintiff F&P Retiree Health Care Fund also brings this action on behalf of a sub-class of third-party payors located in Texas that paid any part of Lipitor's purchase price for its off-label use ("Texas Statewide Class"). The Texas Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and under Texas' Deceptive Trade Practices and Consumer Protection Act, TEX. BUS. & COM. § 17.41-63 ("DTPA").

150. Plaintiffs Laborers' District Council Building and Construction Health and Welfare Fund, and Heavy and Highway Health and Welfare Fund also bring this action on behalf of a sub-class of third-party payors located in Pennsylvania that paid any part of Lipitor's

purchase price for its off-label use ("Pennsylvania Statewide Class"). The Pennsylvania Statewide Class asserts claims for fraudulent misrepresentation, negligent misrepresentation, and under Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTP/CPL"), 73 PA. CONS. STAT. ANN. §§ 201-1 *et seq.*

151. Plaintiffs NYC Sergeants Fund and Sidney Hillman also bring this action on behalf of a sub-class of third-party payors located in New York that paid any part of Lipitor's purchase price for its off-label use ("New York Statewide Class"). The New York Statewide Class asserts claims for fraudulent misrepresentation law fraud, negligent misrepresentation, and violations of N.Y. GEN. BUS. LAW § 349 (Making Deceptive Acts and Practices Unlawful), and N.Y. GEN. BUS. LAW § 350 (Making False Advertising Illegal).

152. The Nationwide Class, the Illinois Statewide Class, the New Jersey Statewide Class, the Florida Statewide Class, the Ohio Statewide Class, the Indiana Statewide Class, the Texas Statewide Class, the Pennsylvania Statewide Class, and the New York Statewide Class are collectively referred to herein as the "Class."

153. Upon information and belief, thousands of third-party payors were induced to pay for Lipitor's off-label use through Pfizer's scheme which illegally promoted the off-label use of the drug. The members of the Class are so numerous and dispersed throughout the United States and the State of Illinois that joinder of all members is impracticable. The Class members can be identified by, *inter alia*, records maintained by Pfizer, drugstores, and PBDMs.

154. Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting solely individual members of the Class. Among the questions of law and fact common to the Class are:

- (a) Whether Pfizer engaged in a scheme to illegally promote the off-label use of Lipitor;

- (b) Whether Pfizer's scheme to promote the off-label use of Lipitor was carried out intentionally with direct knowledge, or at least recklessly by the Company; and
- (c) Whether the members of the Class have sustained damages and, if so, what the appropriate measure of damages should be.

155. The Named Plaintiffs' claims against Pfizer are typical of the claims of the members of the Class as both sustained damages arising out of the Company's wrongful conduct as detailed herein. Specifically, Named Plaintiffs' claims and the Class' claims arise from the Defendant's scheme to illegally promote the off-label uses of Lipitor during the Class Period.

156. The Named Plaintiffs will fairly and adequately protect the interests of the Class and have retained counsel competent and experienced in class action lawsuits. The Named Plaintiffs have no interests antagonistic to or in conflict with those of the Class and should be named as representatives for the Class.

157. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since joinder of all members of the Class is impracticable. Furthermore, because the damages suffered by individual members of the Class may in some instances be relatively small, the expense and burden of individual litigation make it impossible for such class members individually to redress the wrongs done to them. Also, the adjudication of this controversy through a class action will avoid the possibility of inconsistent and possibly conflicting adjudications of the claims asserted herein. There will be no difficulty in the management of this action as a class action.

## VII. COUNTS

### Count I

#### **Violations of the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C. §§ 1961, *et seq.***

158. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

159. The Named Plaintiffs, the members of the Class, Pfizer, physician consultants employed by Pfizer to promote the off-label use of Lipitor, Thomson, PPS, ESLM, and NLEC are each “persons” as that term is defined in 18 U.S.C. § 1961(3).

#### **Participation in the Conduct of Association In Fact Enterprises**

160. For the purposes of this claim Plaintiffs plead that Pfizer conducted the affairs of four association in fact enterprises. These association in fact enterprises were a necessary tool in Pfizer’s illegal marketing scheme. Because it is unlawful for Pfizer to promote the off-label use of drugs, Pfizer needed to create the illusion that organizations separate and independent from Pfizer were touting the off-label use of Lipitor. To effect this goal, Pfizer used association in fact enterprises that purported to be independent of Pfizer but in reality were conducted by Pfizer to market Lipitor for off-label use.

161. The conduct of these four association in fact enterprises affected interstate commerce through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

162. The largest association in fact enterprise consists of: (1) Pfizer; (2) physician consultants employed by Pfizer to promote the off-label use of Lipitor; (3) entities fully funded by Pfizer, including ESLM and NLEC, which had the purpose to improperly increase the sales of Lipitor by promoting the drug’s off-label use; (4) ESLM and NLEC’s sponsors: Thomson/PPS, Convergent Health Solutions, and the Dannemiller Memorial Education Foundation; and (5) other outside marketing/sales firms employed by Pfizer (collectively, the “RICO Participants”)

to promote the off-label use of Lipitor and extract illegal payments from third-party payors for Lipitor's off-label use.

163. Each of the RICO Participants has a systemic link through one another via contractual relationships, financial ties and the coordination of the RICO enterprise by Pfizer. Specifically, ESLM and Pfizer have systematic linkages as Pfizer fully funds the activities of ESLM and, as stated in the Operating Plan, uses ESLM to increase the sales of Lipitor. Following Pfizer's lead, ESLM promotes off-label use of Lipitor. NLEC, like ESLM, also maintains systematic linkages to Pfizer as Pfizer fully funds the activities of NLEC and, as stated in the Operating Plan, uses NLEC to increase the sales of Lipitor. Following Pfizer's lead, NLEC promotes off-label use of Lipitor. Furthermore, NLEC and ESLM are related as they share common personnel in leadership positions.

164. NLEC and ESLM and their respective sponsors knowingly helped Pfizer devise and implement the Company's scheme to illegally promote the off-label use of Lipitor.

165. Additionally, Pfizer and physician consultants and outside marketing/sales firms employed by Pfizer to promote the off-label use of Lipitor to fraudulently extract funds from third-party payors have systematic linkages. Pfizer contracts with and pays these physicians and outside marketing/sales firms to further the RICO association in fact enterprises' scheme to fraudulently increase the sales of Lipitor by promoting off-label uses of the drug. To obtain payment from Pfizer, these entities knowingly helped Pfizer devise and implement its illegal scheme to promote the off-label use of Lipitor.

166. There also exists an association in fact enterprise consisting only of Pfizer, ESLM, NLEC, and the CMEs' respective sponsors. Pfizer conducts the association in fact enterprise to promote Lipitor for off-label use. Pfizer fully funds both entities and provides grant

money and/or consulting fees to the leaders of the CME programs. Furthermore, the CME programs are related as they share common personnel in leadership positions.

167. Furthermore an association in fact enterprise exists between Pfizer, a CME, and its respective sponsor(s). Therefore, an association in fact enterprise exists between Pfizer, NLEC, and PPS and also between Pfizer, ESLM, Convergent Health Solutions, and the Dannemiller Memorial Education Foundation. The members of both association in fact enterprises are connected in a similar manner: Pfizer fully funds both CME programs and provides grant money and/or consulting fees to the leaders of the CME programs.

168. The alleged RICO association in fact enterprises are an ongoing and continuing business enterprise and each person within the enterprise has the common purpose to fraudulently increase sales of Lipitor: (1) inducing physicians to prescribe Lipitor to patients who will not benefit from the drug in order to unlawfully extract payments from third-party payors for off-label uses of Lipitor; and (2) capitalizing on Lipitor's inclusion in drug formularies for on-label uses to extract payments from third-party payors. Without a RICO enterprise, Pfizer could not have perpetuated its scheme to illegally promote the off-label use of Lipitor and extract improper payments from third-party payors for Lipitor's off-label use. During the relevant time period, each of the RICO Participants maintained a separate legal identity while operating the RICO enterprise. Pfizer continues to operate the RICO enterprise by instructing its agents to carry out the objectives of the RICO enterprise as identified herein.

169. Defendant Pfizer has asserted control over each of these association in fact enterprises by placing its agents, employees and/or consultants in positions of control over ESLM and NLEC and by providing funds to all RICO participants to promote Lipitor for off-label use. Pfizer used its position of control over the entities to ensure that Lipitor was promoted

in ways that expanded the patient population from that indicated on Lipitor's label, and these association in fact enterprises did promote Lipitor for off-label use.

170. As manifested in the Operating Plan, Pfizer used NLEC and ESLM as an integral part of its marketing scheme to increase its sales of Lipitor for off-label uses. Pfizer exerted control over these organizations by encouraging their paid consultants to participate in CME courses and promote the off-label use of Lipitor. Pfizer also exerted control over these organizations by funding their activities and providing financial incentives to the organizations' leaders.

#### **Participation in the Conduct of Additional Enterprises**

171. In addition to participating in the conduct of association in fact enterprises, Pfizer participated in the conduct of ESLM and NLEC, both of which are enterprises as defined in 18 U.S.C. § 1961.

172. Because Pfizer could not legally market Lipitor for off-label use, it used ESLM and NLEC, both of which purported to be independent of Pfizer's influence, to market Lipitor for off-label use.

173. Pfizer participated in the conduct of both ESLM and NLEC by fully funding both organizations, placing its agents, employees, and/or consultants in positions of power at the organizations, and providing funding to doctors and physicians who made presentations through ESLM and NLEC.

#### **The RICO Participants' Pattern of Racketeering Activity**

174. Pfizer conducted and participated in the affairs of the RICO enterprises through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. Each RICO Participant

similarly engaged in mail and wire fraud. The scheme likely involved thousands of discrete instances of use of the U.S. mails or interstate wire facilities in furtherance of their scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes a “racketeering activity” within the meaning of 18 U.S.C. § 1961 (1)(B). Collectively, these violations constitute a “pattern of racketeering activity” within the meaning of 18 U.S.C. § 1961(5).

175. The RICO Participants’ racketeering activities amounted to a common course of conduct with a similar pattern and purpose intended to deceive the Class. Each separate use of the U.S. mails and/or interstate wire facilities employed by the RICO Participants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff and the Class. Each RICO Participant engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the RICO enterprise.

#### **The RICO Participants’ Use of the U.S. Mails and Interstate Wire Facilities**

176. The RICO Participants all knowingly promote Lipitor for off-label use to patients for whom drug therapy is not recommended under ATP III guidelines. The RICO Participants perpetrated the RICO enterprise by using the instrumentalities of interstate commerce. As a matter of necessity, in order to generate over \$12 billion of sales yearly, the RICO Participants communicated with one another about the RICO enterprise through the mails (including electronic mail) and the telephone. As detailed above, the enterprise employed a marketing scheme that involved thousands of newsletters, pamphlets, and other marketing material distributed nationwide, including website solicitations to consumers offering to send them Lipitor coupons over the mail; invitations to doctors to attend CME courses; and advertisements directed to consumers, doctors, and PBDMs.

177. Pfizer's illegal conduct and wrongful practices were carried out by several employees, physician consultants, ESLM, and NLEC. These entities worked across state boundaries and necessarily relied upon frequent transfers of documents and information, products, and funds by the U.S. mails and interstate wire facilities to further the goals of the RICO enterprise.

178. The nature and activities of the RICO enterprise was orchestrated by Pfizer from the Company's corporate headquarters in New York. Accordingly, Pfizer's scheme required its headquarters to communicate directly and frequently by U.S. mails and by interstate wire facilities with the RICO Participants.

179. Many of the precise dates of the RICO enterprise's use of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the RICO Participants' books and records. Indeed, an essential part of the successful operation of the RICO enterprise alleged herein depended upon secrecy, and as alleged above, Pfizer took deliberate steps to conceal its wrongdoing. However, given the massive scope of Pfizer's scheme, Pfizer's use of the U.S. mails and interstate wire facilities to perpetrate the RICO enterprise involved thousands of communications.

#### **Pfizer's Motive in Creating and Operating the RICO Enterprise**

180. Pfizer's motive in creating and operating the RICO enterprise and directing the conduct and affairs of the RICO enterprise described herein was to fraudulently increase the off-label sales of Lipitor.

181. The RICO enterprise was designed to, and did, encourage others, including physicians, to advocate the off-label use of Lipitor knowing that third-party payors would rely on physician prescriptions for Lipitor's off-label use and pay for such improper uses of the drug.

#### **Damages Caused by Pfizer's Scheme**

182. Pfizer's violations of federal law and its pattern of racketeering activity have directly and proximately caused the Named Plaintiffs and the Class injuries to their business or property as Plaintiffs, justifiably relying on the belief that Pfizer was behaving legally, have paid many hundreds of millions of dollars for Lipitor's off-label use.

183. Through the use of the RICO enterprise, Pfizer engaged in a pattern of racketeering activity including at least multiple episodes of mail fraud and wire fraud. Third-party payors were injured in their property by reason of these violations, by, among other things, having to unnecessarily pay hundreds of millions of dollars for Lipitor's off-label use. Pfizer and the RICO Participants engaged in numerous overt predicate fraudulent racketeering acts in furtherance of the conspiracy, and thereby directly and proximately caused Plaintiffs' injuries. Third-party payors directly and proximately suffered injuries by unnecessarily paying hundreds of millions of dollars for unwarranted off-label Lipitor use. It was foreseeable that third-party payors would suffer such injuries, because Pfizer and the other RICO enterprise members knew or should have known that third-party payors were the ultimate source of payment for the unwarranted off-label uses Pfizer illegally promoted. Plaintiffs' injuries were direct, resulting from Pfizer's illegal promotion of off-label uses, without which promotion those uses either would not have occurred at all or would have been substantially diminished in number and frequency.

184. Pfizer's use of the mails and wires to perpetrate its fraud involved thousands of communications, including but not limited to, communications with the RICO Participants, physicians, consumers, and PBDMs relating to Pfizer's scheme to illegally promote Lipitor's off-label use.

185. Pfizer's scheme proximately caused injuries to third-party payors. It was foreseeable that doctors would respond to Pfizer's massive marketing blitz by prescribing Lipitor to patients who would not benefit from the drug and in violation of Lipitor's Label. It was foreseeable, and Pfizer intended through its scheme, to deceptively cause third-party payors to pay for medically unnecessary/off-label uses of Lipitor. Plaintiffs would not have made these unnecessary payments had Pfizer not engaged in its pattern of racketeering activity. By reason of the unlawful acts engaged in by Pfizer, the Named Plaintiffs and the Class have suffered damages.

### **Count II** **Unjust Enrichment**

186. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

187. Pfizer's scheme to promote the off-label use of Lipitor unjustly enriched the Company, to the detriment of the Class, by causing Pfizer to receive monetary benefits from third-party payors who were deceived into paying for Lipitor's off-label use.

188. Retention of Plaintiffs' funds by Pfizer for Lipitor's off-label use violates the fundamental principles of justice, equity, and good conscience.

189. Accordingly, Pfizer should be ordered to return any funds obtained as a result of its scheme to the Class.

**Count III**  
**Fraudulent Misrepresentation**

190. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

191. As detailed above, Pfizer made false statements of material fact regarding the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines pursuant to a scheme to cause third-party payors to pay for off-label uses of Lipitor.

192. Pfizer's false statements regarding the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines were knowingly made by the Company to induce physicians to prescribe Lipitor for off-label uses and to, in turn, induce third-party payors to pay for Lipitor's off-label use.

193. All Statewide Class Members similarly relied on Pfizer's misrepresentations promoting the off-label use of Lipitor by paying for Lipitor's off-label use.

194. The Statewide Class Members' reliance on Pfizer's misrepresentations promoting the off-label use of Lipitor was justifiable.

195. As a direct and proximate result of Pfizer's fraudulent misrepresentations, all Statewide Class Members suffered injuries for which monetary damages are sought.

**Count IV**  
**Negligent Misrepresentation**

196. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

197. As detailed above, Pfizer made false statements of material facts regarding the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines which caused third-party payors to pay for Lipitor's off-label use.

198. Pfizer's false statements regarding the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines were carelessly or negligently made by the Company without ascertaining the truth of such statements in order to induce physicians to prescribe Lipitor for off-label uses and to induce third-party payors to pay for Lipitor's off-label use.

199. During the Class Period, Pfizer had a duty to provide accurate information relating to Lipitor's on-label/FDA approved uses.

200. All Statewide Class Members similarly relied on Pfizer's misrepresentations promoting the off-label use of Lipitor by paying for Lipitor's off-label use.

201. The Statewide Class Members' reliance on Pfizer's misrepresentations promoting the off-label use of Lipitor was justifiable.

202. As a direct and proximate result of Pfizer's negligent misrepresentations, the Statewide Class Members suffered injuries for which monetary damages are sought.

**Count V**  
**Illinois' Consumer Fraud and Deceptive Business Practices Act**  
**815 ILL. COMP. STAT. 505/1 *et seq.* (the "Act")**

203. Plaintiffs Southern Illinois L&E, NECA-IBEW, and Midwestern Teamsters H&W repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

204. As detailed above, Pfizer's scheme to illegally promote the off-label use of Lipitor by mischaracterizing the federally approved uses of the drug and the recommendations contained in the ATP III guidelines, caused third-party payors to pay for off-label uses of Lipitor. Pfizer's scheme is a deceptive act or practice which violates the provisions of the Act.

205. Pfizer intended that third-party payors rely on its deception, which occurred during the conduct of a trade or commerce, and pay for off-label uses of Lipitor.

206. The Illinois Statewide Class Members were deceived by Pfizer's deception and paid for Lipitor's off-label use, causing the Statewide Class Members to suffer actual damages.

207. As a direct and proximate result of Pfizer's deception and violations of the Act, the Illinois Statewide Class Members suffered injuries for which monetary damages are sought.

**Count VI**  
**New Jersey Consumer Fraud Act ("CFA")**  
**N.J.S.A. §§ 56:8-1 *et seq.***

208. Plaintiff Local 863 Fund repeats and realleges the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

209. Pfizer conducted an unlawful, fraudulent scheme to promote the off-label use of Lipitor in patients who did not need the drug.

210. As detailed above, Pfizer orchestrated a national marketing campaign that illegally promotes the off-label use of Lipitor by misrepresenting the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines to cause third-party payors to pay for off-label uses of Lipitor.

211. By illegally promoting the off-label use of Lipitor, Pfizer violated the CFA.

212. As a direct and proximate result of Pfizer's violations of the CFA the New Jersey Statewide Class Members suffered injuries for which monetary damages are sought.

213. As a direct and proximate result of Pfizer's deception and violations of the CFA, the New Jersey Statewide Class Members suffered injuries for which monetary damages are sought.

**Count VII**  
**Florida's Deceptive and Unfair Trade Practices Act**  
**FLA. STAT. §§ 501.201, *et seq.* (the "DUTPA")**

214. Plaintiff Plumbers & Pipefitters Fund repeats and realleges the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

215. As detailed above, Pfizer's scheme to illegally promote the off-label use of Lipitor by mischaracterizing the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines caused third-party payors to pay for the drug's off-label use. Pfizer's scheme, which occurred during the conduct of trade or commerce, is a deceptive act or practice which violates the provisions of the DUTPA.

216. The Florida Statewide Class Members suffered losses, because of Pfizer's violations of the DUTPA, by improperly paying for Lipitor's off-label use.

217. As a direct and proximate result of Pfizer's violations of the DUTPA, the Florida Statewide Class Members suffered injuries for which monetary damages are sought.

**Count VIII**  
**Ohio's Consumer Sales Practices Act,**  
**OHIO REV. CODE ANN. §§ 1345.01, *et seq.* ("CSPA")**

218. Plaintiff CB&T Fund repeats and realleges the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

219. As detailed above, Pfizer's scheme to illegally promote the off-label use of Lipitor by mischaracterizing the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines, caused third-party payors to pay for the drug's off-label use.

220. Pfizer's scheme, which occurred during the course of consumer transactions, is a deceptive act or practice which violates the provisions of the CSPA.

221. Pfizer's violations of the CSPA caused Ohio Statewide Class Members to suffer losses as they improperly paid for Lipitor's off-label use.

222. As a direct and proximate result of Pfizer's violations of the CSPA, the Ohio Statewide Class Members suffered injuries for which monetary damages are sought.

**Count IX**  
**Violations of Indiana's Deceptive Consumer Sales Act ("DCSA"),**  
**Ind. Code §§ 24-5-0.5-1, *et seq.***

223. Plaintiff EWBTF repeats and realleges the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

224. At all relevant times, Plaintiff and the Statewide Class Members were "persons" within the meaning of Ind. Code § 24-5-0.5-2(a)(2).

225. At all relevant times, Pfizer was a "supplier" within the meaning of Ind. Code § 24-5-0.5-2(a)(3).

226. At all relevant times, Pfizer's sales of Lipitor to the Indiana Statewide Class Members constituted a "consumer transaction" within the meaning of Ind. Code §24-5-0.5-2(a)(1).

227. At all relevant times, Lipitor was "the subject of a consumer transaction" within the meaning of Ind. Code §24-5-0.5-2(a)(4).

228. At all relevant times, Pfizer's deceptive actions, as described herein, were conducted as part of a scheme, artifice, or device with the intent to defraud or mislead. As detailed above, Pfizer orchestrated a national marketing campaign to illegally promote the off-label use of Lipitor by fraudulently mischaracterizing the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines to cause third-party payors to pay for off-label uses of Lipitor. Pfizer made false statements regarding the federally approved uses of

Lipitor and the recommendations contained in the ATP III guidelines knowing the falsity of such statements and with the intention of defrauding and/or misleading the Indiana Statewide Class Members. Accordingly, Pfizer's conduct is "incurable" as defined by Ind. Code § 24-5-0.5-2(a)(8).

229. By illegally promoting the off-label use of Lipitor, Pfizer violated Ind. Code § 24-5-0.5-3(a)(1) and (2).

230. Plaintiffs are entitled to bring an action against Pfizer under Ind. Code § 24-5-0.5-4.

231. As a direct and proximate result of Pfizer's violations of the DCSA, the Indiana Statewide Class Members suffered injuries for which monetary damages are sought.

232. As a direct and proximate result of Pfizer's deception and violations of the DCSA, the Indiana Statewide Class Members suffered injuries for which monetary damages are sought.

**Count X**

**Texas' Deceptive Trade Practices and Consumer Protection Act ("DTPA"),  
TEX. BUS. & COM. § 17.41-63**

233. Plaintiff F&P Retiree Health Care Fund repeats and realleges the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

234. Plaintiff F&P Retiree Health Care Fund and the other members of the Texas Statewide Class are consumers within the meaning of the DTPA.

235. As detailed above, Pfizer's scheme to illegally promote the off-label use of Lipitor by mischaracterizing the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines caused third-party payors to pay for the drug's off-label use. Pfizer's scheme, which occurred during the conduct of trade or commerce, is a deceptive act or practice which violates the provisions of the DTPA.

236. The Texas Statewide Class Members suffered losses, because of Pfizer's violations of the DTPA, by improperly paying for Lipitor's off-label use.

237. As a direct and proximate result of Pfizer's violations of the DTPA, the Texas Statewide Class Members suffered injuries for which monetary damages are sought.

**Count XI**

**Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTP/CPL")  
73 PA. CONS. STAT. ANN. §§ 201-1 *et seq.***

238. Plaintiffs Laborers' District Council Building and Construction Health and Welfare Fund, and Heavy and Highway Health and Welfare Fund repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

239. The Pennsylvania Statewide Class Members are persons under the UTP/CPL who purchased Lipitor to be used by their beneficiaries primarily for personal and/or family use and are therefore proper Plaintiffs.

240. As detailed above, Pfizer orchestrated a national marketing campaign that illegally promoted the off-label use of Lipitor by mischaracterizing the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines to cause third-party payors to pay for off-label uses of Lipitor.

241. By illegally promoting the off-label use of Lipitor, Pfizer violated the UTP/CPL.

242. The Pennsylvania Statewide Class Members were deceived by Pfizer's misrepresentations and paid for Lipitor's off-label use.

243. The Pennsylvania Statewide Class Members' reliance on Pfizer's misrepresentations was justifiable.

244. As a direct and proximate result of Pfizer's violations of UTP/CPL, the Pennsylvania Statewide Class Members suffered injuries for which monetary damages are sought.

**Count XII**  
**N.Y. GEN. BUS. LAW § 349**  
**(Making Deceptive Acts and Practices Unlawful)**

245. Plaintiffs NYC Sergeants Fund and Sidney Hillman repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

246. As detailed above, Pfizer orchestrated a national marketing campaign that illegally promoted the off-label use of Lipitor by mischaracterizing the federally approved uses of Lipitor and the recommendations contained in the ATP III guidelines to cause third-party payors to pay for off-label uses of the drug. By illegally promoting the off-label use of Lipitor, Pfizer violated N.Y. GEN. BUS. LAW § 349.

247. As Lipitor is a drug intended to be used by consumers, Pfizer's marketing campaign to illegally promote the off-label use of Lipitor was consumer oriented. Pfizer's massive scheme to increase the patient population taking Lipitor was centrally coordinated by Pfizer, spreading a uniform message to doctors, consumers, and PBDMs that Lipitor should be used to treat all patients who were not at their LDL cholesterol goal.

248. As a direct and proximate result of Pfizer's violations of N.Y. GEN. BUS. LAW § 349, the New York Statewide Class members suffered injuries for which monetary damages are sought.

**Count XIII**  
**N.Y. GEN. BUS. LAW § 350**  
**(Making False Advertising Illegal)**

249. Plaintiffs NYC Sergeants Fund and Sidney Hillman repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

250. Pfizer's scheme to promote the off-label use of Lipitor and increase the patient population taking the drug included false and misleading advertisements to doctors, consumers, and PBDMs. The false messages in these advertisements were widespread and uniform, causing doctors, patients, and PBDMs to falsely believe that all patients should be treated to their LDL goal with Lipitor.

251. Pfizer's false and misleading advertisements caused the New York Statewide Class members to pay for medically unnecessary/off-label uses of Lipitor.

252. Pfizer's false and misleading advertisements caused the New York Statewide Class members to suffer injuries for which monetary damages are sought.

**Count XIV**  
**Equitable Accounting**

253. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

254. Named Plaintiffs assert a claim for equitable accounting because they do not have an adequate remedy at law.

255. Through the fraudulent acts identified herein, Pfizer extracted billions of dollars in unjust profits from Plaintiffs.

256. Once the unjust profits were extracted from the Class, Pfizer commingled the ill-gotten funds with legitimate proceeds from on-label sales of Lipitor.

257. Pfizer's commingling of ill-gotten gains with legitimate proceeds from on-label sales of Lipitor concealed (and continues to conceal) the entire value of unjust payments Pfizer extracted from the Class.

258. Accordingly, the Class should be awarded an equitable accounting of all proceeds received from the sale of Lipitor in order to permit Plaintiffs to determine the precise amount of ill-gotten gains Pfizer obtained through its fraudulent scheme.

**Count XV**  
**Civil Conspiracy**

259. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

260. Pfizer entered into an agreement with third party marketers to illegally promote Lipitor for off-label use.

261. The marketers, who knew it was illegal for Pfizer to promote Lipitor for off label use, promoted Lipitor to doctors nationwide for off-label use in furtherance of the conspiracy.

262. The marketers received compensation from Pfizer to promote Lipitor for off-label use.

263. As a direct and proximate result of the conspiracy, Plaintiffs suffered harm as they paid for additional prescriptions of Lipitor.

**PRAYER FOR RELIEF**

WHEREFORE, the Named Plaintiffs demand judgment on behalf of themselves and similarly situated Plaintiffs as follows:

A. Awarding Plaintiffs compensatory damages against Pfizer in an amount to be determined at trial, together with prejudgment interest at the maximum rate allowable by law;

- B. Awarding Plaintiffs treble damages, costs of this suit, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c);
- C. Awarding Plaintiffs any amount by which Pfizer has been unjustly enriched;
- D. Ordering the imposition of a Constructive Trust on all funds Pfizer unjustly obtained from Plaintiffs;
- E. Awarding Plaintiffs punitive or exemplary damages in an appropriate amount to be determined at trial;
- F. Awarding Plaintiffs the costs of this suit, including reasonable attorneys' fees and other disbursements;
- G. Enjoining Pfizer from continuing the illegal and deceptive activities alleged herein;
- H. Ordering Plaintiffs an equitable accounting of Pfizer's proceeds from the Company's sales of Lipitor; and
- I. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

**JURY DEMAND**

Named Plaintiffs demand a trial by jury.

DATED: December 11, 2006

Respectfully submitted,  
CLIFFORD LAW OFFICES, P.C.

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# **EXHIBIT G**

UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

SOUTHERN ILLINOIS LABORERS' AND )  
EMPLOYERS HEALTH AND WELFARE )  
FUND, NECA-IBEW WELFARE TRUST )  
FUND, and MIDWESTERN TEAMSTERS )  
HEALTH AND WELFARE FUND, THE )  
WELFARE FUND OF TEAMSTERS )  
LOCAL UNION 863; PLUMBERS & )  
PIPEFITTERS LOCAL UNION 630 )  
WELFARE TRUST FUND; CLEVELAND )  
BAKERS AND TEAMSTERS HEALTH )  
AND WELFARE FUND; ELECTRICAL )  
WORKERS BENEFIT TRUST FUND; )  
FIRE & POLICE RETIREE HEALTH )  
CARE FUND, SAN ANTONIO, )  
LABORERS' DISTRICT COUNSEL )  
BUILDING AND CONSTRUCTION )  
HEALTH AND WELFARE FUND; )  
LABORERS' DISTRICT COUNCIL )  
HEAVY AND HIGHWAY UTILITY )  
HEALTH AND WELFARE FUND, NEW )  
YORK CITY POLICE SERGEANTS )  
BENEVOLENT ASSOCIATION HEALTH )  
& WELFARE FUNDS, and SIDNEY )  
HILLMAN HEALTH CENTER OF )  
ROCHESTER, individually, and on behalf of )  
all others similarly situated, )

Plaintiffs, )

v. )

PFIZER INC, )

Defendant. )

NO. 06-CV-1818

JUDGE JOHN W. DARRAH

MAGISTRATE JUDGE  
GERALDINE SOAT BROWN

**DEFENDANT PFIZER INC'S MEMORANDUM OF LAW IN SUPPORT OF ITS  
MOTION TO COMPEL PLAINTIFFS TO PROVIDE PROPER RESPONSES TO  
INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS**

## **TABLE OF CONTENTS**

TABLE OF AUTHORITIES.....	ii
PRELIMINARY STATEMENT .....	1
LEGAL STANDARD.....	2
ARGUMENT .....	3
I. THE FUNDS CANNOT DEFEND THEIR FAILURE TO PROVIDE INFORMATION THAT THEY CONCEDE IS DISCOVERABLE.....	5
A. Outstanding Documents.....	5
B. Outstanding Interrogatory Responses.....	7
II. THE FUNDS CANNOT SUPPORT THEIR OBJECTIONS AND REFUSALS TO RESPOND TO OTHER REQUESTS FOR RELEVANT INFORMATION .....	8
A. The Lipitor Prescriptions On Which The Funds Base Their Lawsuit .....	8
1. The Funds concede that this prescription and participant information is essential.....	9
2. The Funds’ objections are meritless.....	10
B. Other Lipitor Prescription Information.....	12
C. Documents Reflecting Reviews Performed By Consultants and Auditors.....	13
D. Fund Formularies and Prescription Drug Benefit Policies .....	13
E. Documents Provided To Fund Participants.....	14
F. Fund Governing Documents and Agreements With Contributing Employers .....	14
CONCLUSION .....	15

## TABLE OF AUTHORITIES

### CASES

<i>Bradley v. Val-Mejias</i> , No. 00-2395, 2001 WL 1249339 (D. Kan. Oct. 9, 2001).....	8
<i>EEOC v. Whitehall Hotel, Ltd.</i> , No. 03 C 6851, 2004 U.S. Dist. LEXIS 25348 (N.D. Ill. Dec. 13, 2004).....	2
<i>Eley v. Herman</i> , No. 1:04-cv-416, 2005 U.S. Dist. LEXIS 30476 (N.D. Ind. Nov. 21, 2005).....	3, 6, 11
<i>Innovative Piledriving Products, LLC v. Oy</i> , No. 1:04-CV-453, 2005 U.S. Dist. LEXIS 14744 (N.D. Ind. July 21, 2005).....	3, 7, 11
<i>Irwin Industrial Tool Co. v. Orosz</i> , No. 03 C 1738, 2004 U.S. Dist. LEXIS 4265 (N.D. Ill. Mar. 17, 2004).....	2
<i>Meyer v. Southern Pacific Lines</i> , 199 F.R.D. 610 (N.D. Ill. 2001) .....	2
<i>In re Thomas Consolidated Industries, Inc.</i> , No. 04 CV 6185, 2005 U.S. Dist. LEXIS 40761 (N.D. Ill. May 11, 2005).....	11
<i>Trading Technologies International, Inc. v. eSpeed Inc.</i> , No. 04 C 5312, 2005 U.S. Dist. LEXIS 10686 (N.D. Ill. Apr. 28, 2005).....	2
<i>U.S. v. Camillo</i> , 233 F.R.D. 520 (S.D. Ill. 2005) .....	12

### STATUTES

Fed. R. Civ. P. 26(a).....	8
Fed. R. Civ. P. 26(b)(1) .....	2
Fed. R. Civ. P. 37(a)(2)(B) .....	2

Defendant Pfizer Inc (“Pfizer”) hereby moves, pursuant to Rules 33, 34, and 37 of the Federal Rules of Civil Procedure (the “Rules”), to compel all twelve Plaintiff Funds (collectively “Plaintiffs” or the “Funds”) to promptly provide compliant responses to Pfizer’s interrogatories and requests for production of documents. Pfizer was waiting to raise Plaintiffs’ many discovery deficiencies until the Court ruled on the pending motion to dismiss, but Plaintiffs’ premature and preemptive discovery motion requires Pfizer to bring before the Court a record of what has actually transpired over the last twelve months.

### **PRELIMINARY STATEMENT**

Although the Funds commenced this action more than a year ago, seeking “billions of dollars” from Pfizer for allegedly off-label Lipitor prescriptions filled by their participants, along with injunctive relief, and although they emphatically opposed Pfizer’s proposal to stay or limit discovery pending Pfizer’s motion to dismiss, the Funds have refused or otherwise failed to provide to Pfizer, or indicate a date by which they will do so, the most relevant and basic information about their claims. Most critically, the Funds still have not identified *even one* of the allegedly off-label prescriptions for which they seek payment from Pfizer, *any* of the participants who filled such prescriptions, or *any* of the physicians who prescribed them. Indeed, the Funds have reneged on prior commitments, and now categorically refuse to produce any of that information.<sup>1</sup> The Funds have also improperly objected to the majority of Pfizer’s interrogatories and document requests, provided incomplete responses to many others, and failed to supplement other responses as promised.

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<sup>1</sup> Ironically, in his April 18, 2007, letter to the Court, the Funds’ lead counsel, Jay W. Eisenhofer, states that the Funds “seek economic damages in the amount they and only they paid for fraudulently induced Lipitor prescriptions,” and that “[t]his is not difficult to ascertain, nor does it depend on third-party conduct.” (Ex. 1 at 2 & n.1.) But, after a year of litigation, the Funds have never provided this information.

During the past nine months, Pfizer has repeatedly followed up on outstanding discovery requests and made numerous attempts to obtain responses without the need for judicial intervention. The Funds, however, have been unwilling to provide essential information and documents or honor their commitments to provide other responses. Further, the Funds have refused to engage in additional meet and confer efforts to resolve these issues. Without the requested information, Pfizer is unable to adequately prepare its defense. Moreover, the Funds' failure to satisfy their discovery obligations threatens to upset the discovery time table established by this Court because Pfizer still does not have documents it should have received last year. Given the Funds' grossly overdue and deficient responses, and their refusal to remedy the deficiencies or even discuss them, Pfizer moves this Court to compel prompt and proper responses.

### **LEGAL STANDARD**

Pursuant to Rule 26, "[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party . . . ." Fed. R. Civ. P. 26(b)(1); *see also* *EEOC v. Whitehall Hotel, Ltd.*, No. 03 C 6851, 2004 U.S. Dist. LEXIS 25348, at \*1-2 (N.D. Ill. Dec. 13, 2004) (Darrah, J.). The standard for relevance under Rule 26 "only requires that [the requested] material lead to the discovery of admissible evidence . . . ." *Irwin Indus. Tool Co. v. Orosz*, No. 03 C 1738, 2004 U.S. Dist. LEXIS 4265, at \*7 (N.D. Ill. Mar. 17, 2004) (Darrah, J.). Rule 37 allows a requesting party to "move for an order compelling an answer" to an interrogatory under Rule 33 or "compelling inspection in accordance with [a] request" for documents under Rule 34. Fed. R. Civ. P. 37(a)(2)(B). Where a request appears relevant, the objecting party bears the burden of showing why its objection or failure to respond is proper. *See Meyer v. S. Pac. Lines*, 199 F.R.D. 610, 612 (N.D. Ill. 2001); *accord Trading Techs. Int'l, Inc. v. eSpeed Inc.*, No. 04 C 5312, 2005 U.S. Dist. LEXIS 10686, at \*2 (N.D. Ill. Apr. 28, 2005).

For example, where a party “resist[s] discovery as unduly burdensome, [it] must ‘adequately demonstrate the nature and extent of the claimed burden’ by making a ‘specific showing as to how disclosure of the requested documents and information would be particularly burdensome.’” *Eley v. Herman*, No. 1:04-cv-416, 2005 U.S. Dist. LEXIS 30476, at \*2-3 (N.D. Ind. Nov. 21, 2005) (citation omitted). Similarly, where a party does not possess or have control over information or documents responsive to a discovery request, it must provide a response clearly stating so. *Id.* at \*6; *see also Innovative Piledriving Prods., LLC v. Oy*, No. 1:04-CV-453, 2005 U.S. Dist. LEXIS 14744, at \*2 (N.D. Ind. July 21, 2005) (“If the served party is unable to supply the requested information, it cannot refuse to answer, but must state under oath that it is unable to provide the information and describe its efforts to obtain this information.”).

### **ARGUMENT**

On June 6, 2006, almost a year ago, Pfizer served the original Funds<sup>2</sup> with its First Interrogatories and First Request for Production of Documents. (*See* Exs. 2, 3.) On July 6, 2006, the original Funds served responses and objections. (*See* Exs. 4-7.) As set out in detail below, in addition to lodging general and specific objections, the original Funds refused to provide substantive responses to many requests. In response to a number of other requests, the original Funds indicated that they would provide the requested information or documents at an unspecified future time. The original Funds responded similarly to Pfizer’s Second Request for Production of Documents. (*See* Ex. 8.) After the Funds amended the Complaint in December 2006, to add nine additional Funds, Pfizer served similar discovery requests on each of the added

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<sup>2</sup> The “original Funds” are: Southern Illinois Laborers’ and Employers Health and Welfare Fund, NECA-IBEW Welfare Trust Fund, and Midwestern Teamsters Health and Welfare Fund.

Funds,<sup>3</sup> and the added Funds provided responses that are similar to, though in a number of cases even less responsive than, those of the original Funds. (See Exs. 9-26.) Although Pfizer has addressed the Funds' objections, refusals to respond, and failure to provide promised responses through multiple letters<sup>4</sup> and several "meet and confer" telephone calls,<sup>5</sup> the vast majority of the Funds' long overdue discovery responses remain outstanding. To make matters worse, the Funds have repeatedly refused to engage in further meet and confer sessions. (See, e.g., Ex. 46 (2/9/07 letter from Margolis to Cheffo); Ex. 40 (3/6/07 letter from Cheffo to Amjed); Ex. 44 (4/6/07 letter from Cheffo to Margolis).)

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<sup>3</sup> The "added Funds" are: Welfare Fund of Teamsters Local Union 863; Plumbers & Pipefitters Local Union 630 Welfare Trust Fund; Cleveland Bakers and Teamsters Health and Welfare Fund; Electrical Workers Benefit Trust Fund; Fire & Police Retiree Health Care Fund, San Antonio; Laborers' District Council Building and Construction Health and Welfare Fund; Laborers' District Council Heavy and Highway Utility Health and Welfare Fund; New York City Police Sergeants Benevolent Association Health & Welfare Funds; and Sidney Hillman Health Center of Rochester.

<sup>4</sup> (See, e.g., Ex. 27 (7/21/06 letter from Mark. S. Cheffo to Sidney S. Liebesman); Ex. 28 (7/25/06 letter from Cheffo to Liebesman); Ex. 29 (7/26/06 letter from Cheffo to Liebesman); Ex. 30 (8/3/06 letter from Cheffo to Jonathan Margolis); Ex. 31 (10/11/06 letter from Cheffo to Margolis); Ex. 32 (1/9/07 letter from Cheffo to Margolis); Ex. 33 (1/10/07 letter from Cheffo to Liebesman); Ex. 34 (1/19/07 letter from Cheffo to Liebesman); Ex. 35 (1/23/07 letter from Cheffo to Liebesman); Ex. 36 (1/24/07 letter from Cheffo to Liebesman); Ex. 37 (2/1/07 letter from Cheffo to Liebesman); Ex. 38 (2/7/07 letter from Cheffo to Margolis); Ex. 39 (2/13/07 letter from Cheffo to Margolis); Ex. 40 (3/6/07 letter from Cheffo to Naumon A. Amjed); Ex. 41 (3/19/07 letter from Cheffo to Margolis); Ex. 42 (3/27/07 letter from Cheffo to Margolis); Ex. 43 (3/29/07 letter from Cheffo to Margolis); Ex. 44 (4/6/07 letter from Cheffo to Margolis); Ex. 45 (4/18/07 letter from Cheffo to Margolis).)

<sup>5</sup> Pursuant to Local Rule 37.2, Pfizer's counsel conferred with the Funds' counsel five times by telephone in good faith attempts to resolve these issues. The dates, times, and participants of those telephonic conferences were: (1) 7/25/06, 3:00 p.m. C.S.T., Mark Cheffo and Andy Jarzyna for Pfizer, and Sidney Liebesman for the Funds; (2) 8/4/06, 10:00 a.m. C.S.T., Cheffo and Jarzyna for Pfizer, and Jonathan Margolis for the Funds; (3) 8/15/06, 11:00 a.m. C.S.T., Cheffo, Hayden Coleman, and Jarzyna for Pfizer, and Margolis for the Funds; (4) 8/24/06, 11:00 a.m. C.S.T., Cheffo for Pfizer, and Margolis for the Funds; and (5) 1/31/07, 6:00 p.m. C.S.T., Cheffo and Jarzyna for Pfizer, and Liebesman and Margolis for the Funds.

**I. THE FUNDS CANNOT DEFEND THEIR FAILURE TO PROVIDE INFORMATION THAT THEY CONCEDE IS DISCOVERABLE**

The Funds have breached their discovery obligations, and prejudiced Pfizer's ability to build its defense, through their unilateral, open-ended extensions of time to produce admittedly discoverable documents and information.

**A. Outstanding Documents**

The Funds have failed to honor commitments – made over nine months ago by the original Funds and nearly four months ago by the added Funds – to produce important documents, including:

- documents received by each Fund from Pfizer or any pharmacy benefit manager (“PBM”) relating to Lipitor (*see* Exs. 7 & 18-26, Nos. 2, 14);
- documents necessary to determine the amount of damages alleged by each Fund (*see id.*, Nos. 8, 9, 10, 41);
- contracts and communications between each Fund and any PBM or other entity concerning payment or reimbursement for Lipitor (*see id.*, Nos. 11, 12, 31, 48);<sup>6</sup>
- documents concerning each Fund's or its PBM's reimbursement or payment practices, procedures, or guidelines with respect to Lipitor (*see id.*, Nos. 15, 16, 17, 18, 19, 20, 27, 32);
- documents containing any statement about Lipitor relied on by each Fund or by any participant who filled a Lipitor prescription for an off-label purpose as defined in the Amended Complaint (hereinafter, the “AC”) (*see id.*, Nos. 29, 30, 33; *see also* Ex. 47 (7/31/06 letter from Margolis to Cheffo), at 5);
- documents regarding the use of Lipitor by Fund participants or the prescription of Lipitor for an off-label purpose as defined in the AC (*see* Exs. 7 & 18-26, Nos. 45, 47; *see also* Ex. 8, Nos. 8, 14, 15, 22; Exs. 18-26, Nos. 68, 74, 75, 82); and
- documents concerning each Fund's claim review process with respect to prescription drug benefits, including with regard to Lipitor claims (*see* Ex. 8, Nos. 12, 13, 20, 25; Exs. 18-26, Nos. 72, 73, 80, 85).<sup>7</sup>

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<sup>6</sup> Although the original Funds have produced certain contracts with PBMs, none of the other nine Funds have produced such contracts.

<sup>7</sup> The Funds have also failed to provide promised responses to a number of other requests. (*See* Exs. 7 & 18-26, Nos. 1, 3, 7, 21; Ex. 8, Nos. 21, 23, 24; Exs. 18-26, Nos. 63, 81, 83, 84.)

During the past nine months, the Funds have produced nothing beyond a single box containing a handful of documents relevant to the three original Funds, two boxes of non-Fund-specific medical literature and apparently misappropriated internal Pfizer documents, and two boxes of redacted pharmacy records from the three original Funds.<sup>8</sup> Pfizer has repeatedly requested that the Funds produce the outstanding documents. (*See supra* notes 4 and 5.) Counsel for the Funds initially indicated that the Funds would provide the documents on a rolling basis as soon as the parties' agreed protective order was entered. (*See, e.g.*, Ex. 48 (10/24/06 letter from Margolis to Cheffo).) But in the over four months since the order was entered on December 14, 2006, the Funds have refused to commit to any timeline for producing the large number of outstanding documents. (*See, e.g.*, Ex. 49 (3/27/07 letter from Margolis to Cheffo).) To stave off a motion to compel, the Funds have claimed, for months, to be "working diligently and in good faith to supplement Plaintiffs' discovery responses expeditiously." (Ex. 46 (2/9/07 letter from Margolis to Cheffo); *see also* Ex. 49 (3/27/07 letter from Margolis to Cheffo).) But their extreme and unexplained delay, and continued refusal to provide dates by which they will produce responses, contradict their declarations of good faith. It is striking that the Funds claim to have paid millions, or even billions, of dollars for off-label Lipitor prescriptions, but have yet to identify even one. Indeed, it is inconceivable that Plaintiffs and counsel could have met their pre-filing investigation obligations without having identified one penny spent by any Fund for an off-label Lipitor prescription. Having taken months purportedly to collect responsive documents, the Funds should immediately produce them and inform Pfizer of any documents that they do not have. *See Eley*, 2005 U.S. Dist. LEXIS 30476, at \*6.

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<sup>8</sup> Notably, the Funds waited to deliver the latter two boxes until April 25, 2007, the eve of the scheduled status conference before this Court, and the day before they moved to compel without warning.

## B. Outstanding Interrogatory Responses

The added Funds have similarly failed to answer many of Pfizer's interrogatories, stating only that, subject to certain general and specific objections, they "reserve[] the right to supplement" their responses. (*See* Exs. 9-17 Nos. 5, 7, 8, 10.) None of the added Funds have identified:

- any persons involved in the decisions to place and retain Lipitor on the Fund formulary (*see* Exs. 9-17, No. 10);
- any PBMs that the Fund has dealt with in the last four years and any Fund personnel responsible for dealing with any PBM during the last ten years (*see id.*, No. 8);
- any persons responsible for reimbursement decisions relating to the Fund's participants since January 1, 2002 (*see id.*, No. 7); or
- any communications between the Fund and Pfizer, or a Pfizer employee, concerning Lipitor, between January 1, 2002, and the present (*see id.*, No. 5).

In addition, five of the nine added Funds have failed to "[i]dentify by name and address any individual or entity that has been employed or retained by the Fund within the last five years as a fund administrator, consultant or auditor." (*See* Exs. 50-54, No. 1.) Each of the five Funds has stated only that, "Plaintiff will provide a response to this request after further research." (*Id.*) Thus, nine of the twelve Funds have not even told Pfizer the names of the individuals who run their operations.

Pfizer has requested supplemental responses to these interrogatories in multiple letters to the Funds' counsel and during the parties' last telephonic meet and confer on January 31, 2007. (*See, e.g.*, Exs. 35, 38, 39, 42.) The Funds' counsel have indicated only that the added Funds intend to supplement their interrogatory responses, without providing a date by which they will do so. (*See* Ex. 46 at 2.) But, "a promise to provide the requested information in the future is not a sufficient response to an interrogatory." *Innovative Piledriving Prods.*, 2005 U.S. Dist. LEXIS 14744, at \*2. Accordingly, the Funds must supplement their answers and "separately

and fully” respond to Pfizer’s interrogatories or “state under oath that they are unable to provide the missing information and describe in detail their diligent efforts to obtain the information.” *Id.* at \*17-18 (quoting Fed. R. Civ. P. 33(b)(1)).

## **II. THE FUNDS CANNOT SUPPORT THEIR OBJECTIONS AND REFUSALS TO RESPOND TO OTHER REQUESTS FOR RELEVANT INFORMATION**

Pfizer is plainly entitled to learn the evidence that the Funds believe support their allegations and causes of actions. *See* Fed. R. Civ. P. 26(a); *see also Bradley v. Val-Mejias*, No. 00-2395, 2001 WL 1249339, at \*1 (D. Kan. Oct. 9, 2001). Because the Funds cannot sustain their categorical refusals to respond to numerous requests targeting those allegations and the elements of their causes of action, they must provide the requested information.

### **A. The Lipitor Prescriptions On Which The Funds Base Their Lawsuit**

The crux of the Funds’ action is that certain of their participants were prescribed, and filled prescriptions for, Lipitor even though the participants were allegedly not proper candidates for Lipitor therapy. (*See* AC ¶¶ 1, 5-16.) The Funds allege that Pfizer should reimburse them for each of those prescriptions. (*See e.g., id.* ¶¶ 183, 187-89, 193-95, 200-02, 206-07.) Pfizer is thus entitled to know, and the Funds must prove, which prescriptions for Lipitor (for which they paid or reimbursed participants) were improper, or off-label, as defined in the AC. Accordingly, in its interrogatories and document requests, Pfizer has requested basic information about, and documentation of, the allegedly off-label prescriptions for which the Funds seek billions of dollars from Pfizer, including: the names of participants who filled Lipitor prescriptions during the relevant time period; the names of participants who were prescribed Lipitor for an off-label purpose as defined in the AC; the names of physicians who prescribed Lipitor to participants for

an off-label purpose as defined in the AC;<sup>9</sup> copies of each Lipitor prescription for which the Funds seek reimbursement; and the amount each Fund has paid for Lipitor prescriptions made for an off-label purpose as defined in the AC. The Funds, however, have objected to every one of these patently relevant requests and refused to provide any of the requested information and documents to Pfizer. (See, e.g., Exs. 4-6, Nos. 1-4, 10; Exs. 9-17, Nos. 1-4, 9; Exs. 7 & 18-26, Nos. 5, 6, 25, 36, 37, 46.) The Funds have similarly refused to produce information that they admit is critical to determine if a prescription is “on-label” or “off-label,” such as: the cholesterol levels and cardiac risk profiles of participants whom the Funds claim received Lipitor for an off-label purpose as defined in the AC; any beneficial health effects for participants who received Lipitor for an off-label purpose as defined in the AC; and other medicines taken by participants that might have affected their cholesterol levels. (See Exs. 7 & 18-26, Nos. 23, 24, 35, 43; Ex. 8, Nos. 6, 7, 11; Exs. 18-26, Nos. 66, 67, 71.)<sup>10</sup>

*1. The Funds concede that this prescription and participant information is essential.*

In their interrogatory responses, the Funds have asserted that “[s]ome medical testing or a review of existing medical tests” will need to be evaluated to determine whether any Lipitor prescription to a Fund participant was written for an off-label purpose as defined in the AC. (Exs. 4-6, No. 15; Exs. 9-17, No. 12 (emphasis added).) And recently, in a motion that the Funds filed in the Southern District of New York, seeking to compel the production of documents from Dr. Robert Jarvik, a nonparty who appeared in certain Lipitor advertisements after the Funds filed

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<sup>9</sup> Although the Funds simultaneously agreed, subject to a number of objections, to produce documents identifying such physicians, they have not done so. (See Exs. 7 & 18-26, No. 7.)

<sup>10</sup> The Funds have also refused to identify any Lipitor advertisement or other statement relied upon by any physician who prescribed Lipitor to a Fund participant for an off-label purpose as defined in the AC. (See Exs. 4-6 & 9-17, No. 6.)

their action,<sup>11</sup> the Funds listed four primary medical factors as necessary to determine whether any Lipitor prescription is off-label, including “a patient’s LDL (bad cholesterol) level” and “a patient’s 10-year probability for developing coronary heart disease.” (Ex. 55 at 3 n.4.)

2. *The Funds’ objections are meritless.*

Nevertheless, when it comes to discovery, the Funds have refused to provide the information, based on boilerplate objections, including claims that the requests are “vague,” “overly broad,” “unduly burdensome,” and “not reasonably calculated to lead to the discovery of admissible evidence,” and that they seek information or documents “in the possession, custody or control of third parties,” and “protected from disclosure by HIPAA, ERISA or any other applicable law or protection.” (See, e.g., Exs. 4-6 Nos. 1-4, 10; Exs. 9-17, Nos. 1-4, 9; Exs. 7 & 18-26, Nos. 5, 6, 23, 24, 25, 35, 36, 37 43; Ex. 8, Nos. 6, 7, 11; Exs. 18-26, Nos. 66, 67, 71.) In letters to the Funds’ counsel on July 21 and 25, 2006, Pfizer addressed these objections in detail. (See Exs. 27, 28.) During a July 25, 2006, telephonic “meet and confer,” counsel for the Funds stated that the Funds themselves did not have the requested participant, prescription, and payment information, and suggested that their PBMs may have much of it. (See Ex. 29 (7/26/06 letter from Cheffo to Liebesman).) Similarly, by letter to Pfizer’s counsel on July 31, 2006, counsel for the Funds stated, “as we understand it, there is no way for Plaintiffs, based on information in their possession, custody or control, to sort from their list of participants those who were prescribed Lipitor for off label purposes.” (See Ex. 47 at 4.) While maintaining their objections to Pfizer’s requests, however, the Funds’ counsel indicated that they would consult

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<sup>11</sup> Dr. Jarvik is one of over fifty nonparties, including the National Institutes of Health and research scientists across the country, who have been victims of the Funds’ overbroad and harassing subpoenas. The Funds seek information about, inter alia, Dr. Jarvik’s personal finances and the compensation he received for appearing in advertisements. (See Ex. 55 at 6.)

with the Funds “to determine whether Plaintiffs are able to produce any of the requested information in some form or fashion or whether, within reason, appropriate protocols can be established to efficiently harvest this information.” (*Id.*) During a meet and confer call on August 4, 2006, the Funds’ counsel further agreed to attempt to obtain the requested prescription information from the Funds’ respective PBMs. However, the Funds’ counsel have never provided the information requested. And in January 2007, each of the added Funds again changed position and served objections refusing to provide the information that counsel was supposedly looking for and willing to provide for the original Funds. (*See* Exs. 9-17, Nos. 1-4, 9; Exs. 18-26, Nos. 5, 6, 23, 24, 25, 35, 36, 37, 43, 46.)

Of course, the Funds cannot support their contention that Pfizer’s requests for this information are unduly burdensome: “Asking a party to set out its factual support for allegations it included in its own complaint is not unduly burdensome.” *In re Thomas Consol. Indus., Inc.*, No. 04 CV 6185, 2005 U.S. Dist. LEXIS 40761, at \*19 (N.D. Ill. May 11, 2005). And although the Funds have suggested that some of the requested information may be held by third parties, such as their PBMs, the Funds’ own discovery responses (including the original Funds’ contracts with their PBMs), as well as documents produced by several nonparties, indicate that the Funds do, in fact possess, control, or have the right to request, such information. (*See, e.g.*, Ex. 35 (1/23/07 letter from Cheffo to Liebesman).) Furthermore, if the Funds themselves do not possess or have the right to obtain information or documents responsive to these requests, they must provide a response clearly stating so. *Eley*, 2005 U.S. Dist. LEXIS 30476, at \*6; *see also Innovative Piledriving Prods.*, 2005 U.S. Dist. LEXIS 14744, at \*2.

The Funds’ objections to these requests on privacy or HIPAA grounds also cannot stand. Notwithstanding the fact that the Funds placed their participants’ medical information squarely at

issue by bringing a lawsuit for reimbursement of allegedly off-label prescriptions, and later agreed to produce this information, the parties' agreed confidentiality order ensures the confidential treatment of participant health information and allows its disclosure to Pfizer. *See U.S. v. Camillo*, 233 F.R.D. 520, 522 (S.D. Ill. 2005) ("HIPAA permits protected health information to be revealed in response to a discovery request, if the parties . . . have asked the Court for a protective order."). Moreover, available documents confirm that the Funds' own written policies expressly allow them to disclose the requested information for a number of purposes, including to obtain reimbursement. (*See, e.g.*, Ex. 56 (Southern Illinois Laborers' & Employers Health & Welfare Fund Summary Plan Description 2005 at 53-54).)

#### **B. Other Lipitor Prescription Information**

The Funds have also refused to provide the names of participants who were denied reimbursement for Lipitor prescriptions or documents reflecting payments made by the Funds for Lipitor after this lawsuit was commenced. (*See* Exs. 7 & 18-26, Nos. 26, 28, 55; Ex. 8, No. 17; Exs. 18-26, No. 77.) These requests bear directly upon issues of statutes of limitations, damages, and reliance. The Funds repeatedly claim that they would have taken steps to restrict their reimbursement for Lipitor prescriptions had they been aware of the conduct and statements they allege in the AC. (*See* AC ¶¶ 75-77.) Accordingly, Pfizer is entitled to conduct discovery to determine if that allegation has factual support and what, if any, changes the Funds have made with regard to reimbursement for Lipitor after they became aware of Pfizer's alleged conduct and statements and filed this lawsuit. If the Funds continued to pay for allegedly off-label Lipitor prescriptions after the alleged scheme was exposed, such conduct would be highly probative and would squarely undercut each of their claims, as well as their credibility. The Funds have not shown that it would be unduly burdensome to produce this basic information.

**C. Documents Reflecting Reviews Performed By Consultants and Auditors**

The Funds have also refused to identify, or produce the reports or analyses of, any consultants, accountants, or auditors engaged by the Funds to provide services relating to their prescription drug benefit plans. (*See, e.g.*, Exs. 7 & 18-26, Nos. 53, 54, 59, 60; Ex. 8, No. 16; Exs. 18-26, No. 76.) Such entities are very likely to have discoverable information about the Funds' expenditures for Lipitor and their alleged damages. And any third-party evaluations of the Funds' prescription drug benefit and payment practices or policies are likely to bear directly on the Funds' central allegations of over-payment for Lipitor prescriptions. Indeed, the few reports Pfizer has obtained from nonparty consultants are less than forty pages long, were mailed directly to the Funds, and contradict claims made by the Funds in the AC. The Funds cannot establish that it would be unduly burdensome for them to merely identify such parties and produce any reports or analyses in their possession.

**D. Fund Formularies and Prescription Drug Benefit Policies**

The Funds have also refused to provide, on relevance and undue burden grounds, information and documents relating to their prescription drug formularies and reimbursement policies and practices, including: documents identifying the medicines contained on their formularies for the past four years and any restrictions or requirements placed on any formulary medicine; the names of all statins (cholesterol-lowering medicines) other than Lipitor for which the Funds have provided payment or reimbursement to moderate-risk participants; and the names of medicines for which the Funds have taken steps to ensure that they are used in a cost-effective manner, as well as the steps taken. (*See* Exs. 7 & 18-26, Nos. 51, 52; Ex. 8, No. 5, Exs. 18-26, No. 65; Exs. 4-6, Nos. 12, 14; Exs. 9-17, No. 11.) The Funds allege that they have the right to determine the content and structure of their formularies and claim that they would have placed

restrictions on Lipitor if they had been aware of Pfizer's alleged conduct and statements. (*See* AC ¶¶ 75-77.) Accordingly, Pfizer is entitled to obtain information about the Funds' formularies and the nature of restrictions they have placed on other medicines. Based on the original Funds' limited document production, this information is readily available to the Funds.

#### **E. Documents Provided To Fund Participants**

Asserting relevance, privilege, and other boilerplate objections, the Funds have similarly refused to produce documents that they or others have provided to their participants about this lawsuit, Lipitor, or the healthcare and prescription drug benefits they offer. (*See* Exs. 7 & 18-26, Nos. 4, 22, 49; Ex. 8, Nos. 1, 26; Exs. 18-26, Nos. 61, 86.) The Funds' objections are meritless. The AC raises a number of issues about prescription drug benefits provided to Fund participants, and seeks reimbursement for certain Lipitor prescriptions filled by participants. Accordingly, Pfizer is entitled to review documents in the Funds' possession that have been provided to their participants about those benefits, Lipitor, or this lawsuit. The Funds cannot withhold documents on privilege grounds because their participants are neither parties to this litigation nor agents of the Funds.

#### **F. Fund Governing Documents and Agreements With Contributing Employers**

The Funds have also refused to produce documents: relating to Fund governance; identifying the employers who provide financial support to the Funds; or reflecting any agreements with those employers about medical and prescription drug benefits. (*See* Exs. 7 & 18-26, Nos. 38, 58; Ex. 8, Nos. 9, 10; Exs. 18-26, Nos. 69, 70.) The Funds cannot support their relevance and undue burden objections. The AC alleges, and other available public information indicates, that most, if not all, of the Funds were created through collective bargaining agreements with employers or local unions and are funded through employer contributions. (*See*,

*e.g.*, AC ¶¶ 5-16.) Accordingly, the identity of those employers, and the nature of those agreements, are plainly relevant to the Funds' action to recover money they have allegedly incurred pursuant to such relationships and agreements. Pfizer is entitled to discover whether the Funds are the actual parties in interest or whether some or all of any of the alleged payments for Lipitor were actually made by employers who have standing. This information is also necessary for Pfizer to evaluate and distinguish the Funds, including based on the pharmacy benefit plans they offer and any restrictions they impose on Lipitor reimbursement, for purposes of opposing any class certification motion.<sup>12</sup> The Funds cannot credibly claim that it would be unduly burdensome to identify their contributing employers and produce the collective bargaining agreements upon which the Funds are founded and operate.

### **CONCLUSION**

For the foregoing reasons, Pfizer respectfully requests that this Court grant Pfizer's motion and enter an Order directing the twelve Funds to promptly provide complete and proper responses to all outstanding discovery requests, including all those cited above, and awarding Pfizer attorneys' fees and costs pursuant to Rule 37(a)(4)(A).

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<sup>12</sup> The Funds agreed to sign a stipulation indicating that they would file a motion for class certification, if any, within sixty days of a decision on Pfizer's motion to dismiss. As with other commitments, however, they have retreated and will not say when, if ever, they plan to move for certification.

DATED: April 30, 2007

Respectfully submitted,

**PFIZER INC**

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**CERTIFICATE OF SERVICE**

I, Andrew J. Jarzyna, an attorney, certify that on this 30th day of April, 2007, one true and correct copy of the foregoing Defendant Pfizer Inc's Memorandum of Law in Support of its Motion to Compel Plaintiffs to Provide Proper Responses to Interrogatories and Requests for Production of Documents was served through this Court's electronic filing system upon the following counsel for Plaintiffs: George S. Bellas, gsb@cliffordlaw.com; Robert A. Clifford, rac@cliffordlaw.com; Sidney S. Liebesman, sliebesman@gelaw.com; Patrick J. O'Hara, patrick@cavanagh-ohara.com; and Thomas K Prindable, tkp@cliffordlaw.com.

/s/Andrew J. Jarzyna  
Andrew J. Jarzyna

# **EXHIBIT H**

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS (Chicago)

SOUTHERN ILLINOIS LABORERS'	)	
AND EMPLOYERS HEALTH AND	)	
WELFARE FUND, et al.,	)	
	)	
Plaintiffs,	)	
v.	)	Docket No. 06-CV-1818
	)	
PFIZER, INC.,	)	Chicago, Illinois
	)	June 13, 2007
Defendant.	)	

CONTINUED HEARING ON MOTIONS  
BEFORE THE  
HONORABLE MAGISTRATE JUDGE GERALDINE SOAT BROWN

APPEARANCES:

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produced by transcription service.

1 THE CLERK: 06-C-1818, Southern Illinois Laborers and  
2 Employers Health and Welfare Funds vs. Pfizer.

3 THE COURT: Counsel, will you come to the podium,  
4 please. State your name, spell your last name and state the  
5 client that you represent.

6 MR. GRYGIEL: Steve Grygiel of Grant & Eisenhofer for  
7 the plaintiffs.

8 THE COURT: And how do you spell your last name?

9 MR. GRYGIEL: G-r-y-g-i-e-l.

10 THE COURT: All right.

11 MR. CHEFFO: Good afternoon, your Honor, Mark  
12 C-h-e-f-f-o of Skadden Arps for Pfizer.

13 THE COURT: And how do you pronounce that?

14 MR. CHEFFO: Sheffo, your Honor. Like S-h.

15 THE COURT: Okay. All right.

16 MR. JARZYNA: Andy Jarzyna, J-a-r-z-y-n-a, also from  
17 Skadden, also representing Pfizer.

18 THE COURT: All right. Well, we're here on the  
19 continued hearing on the motions. And I had ordered the  
20 parties to do supplemental Rule 26.(a)(1) disclosures by the  
21 1st of June and to list by the 4th of June the outstanding  
22 disputes with reference to the motions and exhibits.

23 I received first a notice of outstanding discovery  
24 disputes from the defendant indicating that everything was  
25 still disputed among the five or six inches of documents that

1 had previously been submitted to the Court, and then I received  
2 defendant Pfizer's supplement to its notice of outstanding  
3 discovery disputes indicating that some had been supplemented,  
4 some had not. We can get into that further detail and will in  
5 a few minutes, but I did not receive anything from the  
6 plaintiffs in connection with the plaintiff Teamsters Local  
7 863's motion to compel.

8 MR. GRYGIEL: Your Honor, I submitted a letter to the  
9 Court on the deadline and --

10 THE COURT: Letters are not filings.

11 MR. GRYGIEL: Yes. I apologize, your Honor.

12 THE COURT: I mean I don't have it.

13 MR. GRYGIEL: I understood you had asked for a  
14 letter.

15 THE COURT: No.

16 MR. GRYGIEL: And that's what we did. My understand-  
17 ing was actually it had been received. I have not, by the way,  
18 gotten the supplemental response you just referred to. That's  
19 news to me about what's --

20 THE COURT: I mean --

21 MR. GRYGIEL: -- still in dispute.

22 THE COURT: I don't accept letter submissions on  
23 substantive matters.

24 MR. GRYGIEL: I apologize, your Honor. If you have a  
25 cover letter for something, that's one thing. If you -- Well,

1 that's basically the only material other than settlement  
2 letters that I will accept by way of letter. Everything that  
3 is substantive has to go on the record, and I think I made that  
4 pretty clear. I would not have said a letter. I am quite  
5 clear.

6 But in any event, I don't have it. I didn't consider  
7 it. The defendant Pfizer's supplement was received and was  
8 actually filed as Docket 91 on the docket on the 8th of June.

9 MR. CHEFFO: If I could, your Honor, just to clarify.  
10 Steve, the supplement was really just we went through what you  
11 had given us and just tried to spell out for the Court so your  
12 Honor wouldn't have to waste as much time on issues that had  
13 been resolved, and I think I actually did receive his letter  
14 and just for the substance, because it may make the Court's  
15 life (inaudible) easier, I believe what Mr. Grygiel indicated  
16 was that all the issues regarding his motion for documents had  
17 been -- We had resolved them.

18 And I think similarly, if I could, your Honor, I know  
19 you may want to direct how you'd like us to handle this, but I  
20 think there's three major issues here, you know, documents --  
21 Or actually four. Documents; interrogatories; admissions and  
22 Rule 26. I think -- And Mr. Grygiel will correct me -- with  
23 respect to documents the parties have both, as per your  
24 direction, we've met and conferred both on electric and paper  
25 documents, and while we certainly are not done with our

1 dealings with each other on this, I think we've taken off the  
2 table any motion practice with respect to documents based on  
3 our understanding that we're going to continue to do timely  
4 searches and exchange of document information. Then --

5 THE COURT: Okay, so let me pause there.

6 MR. CHEFFO: Yes.

7 THE COURT: Then that would mean that plaintiff  
8 Teamster Local 863's Motion to Compel, Docket No. 68, and  
9 Defendant's Motion to Compel with respect to documents, which  
10 is Docket No. 74, are both moot.

11 MR. CHEFFO: With one minor exception. I'd think  
12 we'd just like some guidance from the Court perhaps on some  
13 deadlines. So in other words while Mr. Grygiel, again in good  
14 faith has indicated that plaintiffs will continue to provide  
15 documents and Pfizer has done the same, to the extent that at  
16 some point in this hearing we could maybe reach either agree-  
17 ment or get some guidance from the Court about some deadlines  
18 and those issues, you know, that might be helpful. But I  
19 frankly don't think there's a lot of dispute about that because  
20 I know that we're both very aware of the upcoming deadlines and  
21 are working very diligently to try and exchange documents.

22 THE COURT: All right, so what you're saying -- Is  
23 that consistent with your understanding, too, Mr. Grygiel?

24 MR. GRYGIEL: That it is, your Honor, yes.

25 THE COURT: Okay. Well, good. Then --

1 MR. GRYGIEL: Essentially (inaudible) we're working  
2 it out. We've been talking quite a bit. In fact, perhaps more  
3 than quite a bit, quite regularly, and all the sand is staying  
4 in the sandbox, and we're exchanging documents.

5 Now Mr. Cheffo clearly doesn't have everything he  
6 wants from us, although since the last time we were here we  
7 have produced, I think, an additional 15,000 pages. Most of it  
8 comes from one client, I agree, 14,392 pages from one client  
9 and another 192, I think, from another. We have others,  
10 obviously, to go, and we have more documents yet to produce.  
11 Mr. Cheffo is telling me, yes, we have more documents to  
12 produce to you, too, and that's something we're working on and,  
13 I think, making progress on.

14 With respect to the further course of document  
15 discovery, I think at this point we can simply hold in abeyance  
16 any ruling on those motions or any need to discuss them. They  
17 are for all practical purposes, I think, moot. We're working  
18 on it. We may have disputes in the future. I don't think we  
19 have any today.

20 THE COURT: Okay. Well then, I'm going to moot those  
21 motions because even if further discussions break down the  
22 issues will be so narrowed that the previous motions will be  
23 effectively outdated and I'm not going to wade through 20  
24 discovery disputes in order to resolve one. So those motions  
25 will be moot.

1           Now in terms of your document production, I under-  
2 stand it's a big task in this case. There are a lot of  
3 plaintiffs. There's a lot of documents on the defendant's  
4 side. I would like to get some structure about it in terms of  
5 deadlines and what I am thinking is that in this case it would  
6 be parties exchanging letters as of a date we would pick, in  
7 which you would advise of the status of your compliance and  
8 what further search needs to be undertaken. And perhaps the  
9 date to do that is by the end of this month, the 29th? Is that  
10 too -- How does that sound to the parties?

11           MR. CHEFFO: Maybe if we can get the following weeks.

12           THE COURT: Okay, fine.

13           MR. CHEFFO: I have some scheduled (inaudible).

14           MR. GRYGIEL: That's fine, your Honor.

15           THE COURT: The following week, of course, is the 4th  
16 of July. I'm happy to -- It's not my burden -- I'm happy to  
17 set July 6th as the date in which you each serve each other by  
18 letter a status report regarding the status of your production  
19 and the outstanding searches that will need to be completed and  
20 a proposed schedule for those searches.

21           MR. GRYGIEL: That's perfectly fine, your Honor, as  
22 long as I think we all understand it. In the interim, of  
23 course, no one is laying down.

24           MR. CHEFFO: No.

25           THE COURT: Right.

1 MR. GRYGIEL: We're going to continue to talk to each  
2 other --

3 THE COURT: Right. Right.

4 MR. GRYGIEL: -- and (inaudible) talks to discuss  
5 (inaudible).

6 MR. CHEFFO: Absolutely.

7 THE COURT: All right.

8 MR. CHEFFO: That's our intention.

9 THE COURT: But just you have a status report by  
10 then.

11 MR. CHEFFO: Right.

12 THE COURT: All right, so --

13 MR. CHEFFO: That's --

14 THE COURT: -- then with respect to those, two  
15 motions are moot. The parties agree that they will continue  
16 their production of documents and working to resolve any  
17 outstanding disputes. No later than July 6th, 2007, the  
18 parties shall each serve a -- Let's put it this way: The  
19 plaintiffs' counsel and defendant's counsel shall exchange  
20 letters reporting on the status of their document production  
21 including any remaining searches to be completed and proposed  
22 schedule for the completion of those searches. All right,  
23 good.

24 MR. GRYGIEL: Yes, your Honor.

25 THE COURT: So that takes care of those two. Good.

1 MR. CHEFFO: And I think in the same vein if we can  
2 address the issue of admissions first, I think that --

3 THE COURT: Okay.

4 MR. CHEFFO: -- be something that your Honor could  
5 probably deal with easily today. Basically, you know, there's  
6 been a multiple series of admissions served by Pfizer. Many of  
7 them go back to literally 12 months or so ago. Within the last  
8 two weeks Mr. Grygiel and his team apparently have been at work  
9 at supplementing. So they have supplemented multiple sets of  
10 admissions and provided those to us, and I think as to the  
11 documents, the substance of the documents that they supple-  
12 mented we have no issues with those. I think they meet the  
13 standard. I think they're fair.

14 THE COURT: Good.

15 MR. CHEFFO: There is a subsequent set that was  
16 served on us, the responses were served on us on April 16, and  
17 again Mr. Grygiel will speak for himself in this. He has  
18 represented that, like the other sets, he has an expectation of  
19 supplementing those. We identified the deficiencies. We  
20 haven't yet received those. I suspect it's probably just a  
21 timing issue but you can tell me if I'm wrong.

22 MR. GRYGIEL: Exactly right. I know that yesterday  
23 we served supplements to the second request for admissions and  
24 you should have received those. Are you speaking of a third  
25 set?

1 MR. CHEFFO: Well, there were some that were on April  
2 16th that were -- you had responded to.

3 MR. GRYGIEL: (Inaudible)?

4 MR. CHEFFO: I can send them --

5 MR. GRYGIEL: It's a bit of a blur, your Honor, but I  
6 believe that we have responded to all the requests for  
7 admissions. There were 55 discrete ones in the first set and  
8 15 in the second, and I thought you got the supplemental ones,  
9 Mark, last night. I might be wrong, but if there's any out  
10 there and they need supplementing and you send a letter that  
11 outlines the deficiencies, we'll take care of it the same way  
12 we took care of the other ones.

13 THE COURT: Okay. Are there any ones that are  
14 disputed that are ripe for argument today?

15 MR. CHEFFO: The answer, I think, is no. But I do  
16 want to put a footnote down, your Honor, on this because, you  
17 know, obviously I think both Mr. Grygiel and I want to be  
18 candid to the Court and I think we frankly have a little bit of  
19 a new life in this case and our ability to work out issues  
20 whereas perhaps that didn't exist before.

21 Having said that, you know, I think we do need to  
22 take a step back and we can deal with it now or perhaps later  
23 in the hearing, but I think it's very important for the Court  
24 to be mindful of really what has happened here. In other  
25 words, I know you've read many of the letters and (inaudible)

1 this case was filed back in March of 2006. We expeditiously  
2 served discovery. Much of the discovery we're talking about  
3 that had been done literally in two weeks was discovery and  
4 responses that we served 12 months ago. So from a procedural,  
5 case management and equity position, I think while I can't tell  
6 your Honor that the actual responses are deficient today, what  
7 I certainly can tell you is that I believe Pfizer has been  
8 significantly prejudiced by the fact that we've had to get to  
9 this point 14 months after the litigation has essentially been  
10 pending, and five and a half months before, you know, a  
11 deadline in a, quote, unquote, "\$40 billion case."

12 And I do think that there is something. This goes  
13 for particularly some of the interrogatory responses and  
14 admissions.

15 THE COURT: I'm sorry, what is the five months?

16 MR. CHEFFO: Well --

17 THE COURT: You have discovery closes March 31st?

18 MR. GRYGIEL: No. We have currently, as I understand  
19 it, your Honor, the December 31st is the fact cutoff date.  
20 March 31st is only for experts.

21 THE COURT: Okay, well, that could be the case.  
22 Well, except that's not, I think, what the docket reflects.

23 (Addressing the Clerk or the Law Clerk:) Would you  
24 get the docket?

25 (Inaudible conversation.)

1 THE COURT: All right. So you've got, basically  
2 you've got the next six months.

3 MR. CHEFFO: Anyway, and as I say, I think that, you  
4 know, I (inaudible) to address it now, I think there's a number  
5 of remedies that the Court could consider and we would urge the  
6 Court to consider. You know, I think putting aside sanction  
7 issues which is something certainly the Court can consider,  
8 that's not necessarily going to help my client per se. What I  
9 think we're facing is had I had many of these responses,  
10 literally nine or ten months ago I think this case would have  
11 been dramatically different. And I can just -- I'd like to  
12 actually go through a few --

13 THE COURT: Well, what is your bottom line? What are  
14 going to ask --

15 MR. CHEFFO: Well --

16 THE COURT: -- the Court to do?

17 MR. CHEFFO: Well, I think that there have been  
18 significant discovery abuses by the plaintiff. I mean these  
19 are -- Much of the answers that they've given us are things  
20 like, is Lipitor on your formulary? Now we know yes, they've  
21 admitted it, and interrogatories about various information that  
22 was available to them 12 months ago. And I guess, your Honor,  
23 where we are is discovery is supposed to proceed in a normal,  
24 orderly way. We serve our discovery. If we have disputes we  
25 meet and confer. We've been, you know, writing letters and

1 asking for it and now, in two weeks -- And I think it's  
2 evidence that with a good-faith, diligent effort as Mr. Grygiel  
3 has undertaken, all of this could have been done in two weeks.  
4 There's nothing here that's insurmountable.

5 THE COURT: Okay, well, give me the bottom line.

6 MR. CHEFFO: Well --

7 THE COURT: What is it that you're going to be --

8 MR. CHEFFO: Well, I think, your --

9 THE COURT: -- asking me to do?

10 MR. CHEFFO: I think there's a few things. I think  
11 one is this has been an extensive cost for Pfizer to pursue  
12 relief in this case. We've ultimately received it now but I  
13 think the costs have been exceptional, both in letter writing  
14 and motion practice. I also believe that from a perspective of  
15 discovery deadlines to the extent that we would just seek a  
16 modest extension. I think Pfizer should have a period of time,  
17 three or four months, where its discovery deadline is extended  
18 but the plaintiffs' isn't, and the reason there is had they  
19 done what they were supposed to do four or five months ago --  
20 See, we're in a situation that we're now the deadlines are  
21 upcoming and they didn't do anything for 12 months. They all  
22 of a sudden dump all of this information on us, albeit most of  
23 it is responsive at this point.

24 But had they done that 12 months ago everything that  
25 I now have to do now in the next five-and-a-half months I could

1 have been doing for the last 12 months. And I think that's  
2 incredibly prejudicial.

3 THE COURT: Okay, let me make a couple of points  
4 here.

5 MR. CHEFFO: Yes, your Honor.

6 THE COURT: Number one is that Judge Darrah's  
7 discovery schedule cannot be moved by me. If he has set a  
8 deadline of December 31st any relief you have to seek has got  
9 to be sought from him.

10 The second thing is just as a matter of practical  
11 fact, while you can come in at this point and say we are going  
12 -- It looks like we're going to need more time, I think it is  
13 unlikely in the abstract that Judge Darrah is going to say  
14 well, here we are in June, it's certainly a certainty you can't  
15 make a December cutoff. I think it is much more likely that he  
16 would be receptive, as any judge would be, to a plan of  
17 discovery. And if that plan of discovery, including scheduling  
18 depositions of people that had to take place in the second half  
19 of the year rather than the first half of the year, indicates  
20 that there's going to be difficulty meeting the deadline, at  
21 that point he would be more receptive to an extension than one  
22 just sort of in the abstract: We don't think we're going to be  
23 able to do it.

24 Because six months can be a reasonable amount of time  
25 depending upon what there is to do. What is the task? Are

1 there 27 depositions? Are there six? I mean this kind of  
2 thing is what needs to be planned and then a modest extension,  
3 if the plan reflects that's a necessity, is much more likely to  
4 be granted by any judge.

5 MR. CHEFFO: Okay, your Honor. I've articulated -- I  
6 think that the consideration you're concerned about is  
7 ultimately what will probably happen is an extension of all  
8 parties' discovery and my point is I just think that's unfair  
9 to Pfizer --

10 THE COURT: Well --

11 MR. CHEFFO: -- it's been proceeding (inaudible) pace  
12 and maybe it's an issue that we need to deal with in a few  
13 months. I just really wanted to state it for the record  
14 and --

15 THE COURT: It's out there. It's out there but what  
16 we need to do is we need to have a plan. And we should all  
17 anticipate that the deadline will not be moved. I think that's  
18 very important. It's a mistake for parties to assume any  
19 particular ruling from a judicial officer, and so you should  
20 anticipate the deadline won't be moved unless you can show a  
21 good cause to do it. So that now you're over the major bottle-  
22 neck in the process of the case, now it's time to evaluate what  
23 you have and then go on to the next phase, which is going to be  
24 oral discovery, I would assume.

25 MR. CHEFFO: Yes, your Honor, I think that's right.

1 And I think I understand what your Honor's views are. Unless  
2 Steve has, you know, so I was going to just go (inaudible) that  
3 there are some disputes on --

4 THE COURT: Okay.

5 MR. CHEFFO: -- and (inaudible). So I think, to  
6 recap, documents admissions, I think, either I have them or I  
7 will have them so that's something that the substance to be  
8 clear, the substance of Mr. Grygiel's and the plaintiffs'  
9 responses at this point from what I've seen, I believe comport  
10 with the rules and meet our requests.

11 I gave a copy of this to Mr. Grygiel. I'm just going  
12 to give a copy to your Honor.

13 THE COURT: For the record, counsel is handing me  
14 something entitled Table 6 NCEP Treatment Guidelines: LDL-See  
15 Goals and Cut Points for Therapeutic Lifestyle Changes and Drug  
16 Therapy in Different Risk Categories. So I'm going to mark  
17 that today's date, which is June 16th, 2007. So what is this  
18 about?

19 MR. CHEFFO: This is -- I don't want to spend a lot  
20 of time with the substance and the facts of the case but I  
21 think that it will inform your Honor's consideration of some of  
22 the issues if we just have this chart, and basically this chart  
23 is really what this case is about. And this, the NCEP is the  
24 National Cholesterol Education Program.

25 This chart is in the Lipitor label, okay?

1 Plaintiffs' claim, your Honor, is that there's various columns  
2 here. If you were a person, a man or a woman, who has two-plus  
3 risk factors, starting from the left, if you have an LDL level  
4 of between 130 and 159, so I'm in the middle section here, and  
5 your 10-year risk profile, in other words your 10-year risk of  
6 having a coronary event is less than 10 percent, it's the  
7 plaintiffs' position that the only appropriate remedy is to  
8 have TLC, which is therapeutic lifestyle changes. And the  
9 plaintiffs allege that Pfizer, in some way, promoted or  
10 encouraged patients to take and, I suspect, physicians to  
11 write, prescriptions for Lipitor for that relatively narrow  
12 class of people called moderate risk patients. And therefore,  
13 they claim, that that is an off-label promotion. The reason  
14 why --

15 THE COURT: Let me stop you.

16 MR. CHEFFO: Yes, please.

17 THE COURT: Mr. Grygiel, is that -- Would that be an  
18 admitted limited -- but does what Mr. Cheffo said accurately  
19 characterize at least of portion of your claim?

20 MR. GRYGIEL: A portion. And what the case is about  
21 isn't this chart. What the case is about is off-label market-  
22 ing which goes beyond simply looking at Table 6 and saying oh,  
23 that's it. There's obviously a lot more to it and the amended  
24 complaint speaks quite clearly to what that is, and in fact,  
25 describes documents that show that Pfizer was indeed doing

1 off-label marketing.

2 MR. CHEFFO: Well --

3 THE COURT: Okay, I just wanted to make --

4 MR. CHEFFO: That's how we got -- (inaudible,  
5 multiple voices) --

6 THE COURT: -- sure I understand what this case is  
7 about.

8 MR. CHEFFO: Yes.

9 THE COURT: And I understand it's off-label  
10 marketing. And the gist of it is that the plaintiffs believe  
11 that the defendant encouraged too much prescribing of Lipitor.

12 MR. GRYGIEL: Encouraged is a gentle word, your  
13 Honor, but yes, that will work.

14 THE COURT: Okay.

15 MR. CHEFFO: And your Honor, you know, I'm happy to  
16 have Mr. Grygiel say I can pull out the complaint and show you.  
17 I think that it is about marketing but it's, you know, it's not  
18 just marketing in the air, you know, it is -- The claim very  
19 specifically talks about and it's defined in the amended  
20 complaint as this moderate risk class, two or more risk  
21 factors, 130 to 159, and less than 10 percent risk factor,  
22 because those are the only folks, according to the plaintiffs,  
23 at which LDL -- at which TLC should be considered as an  
24 alternative to Lipitor.

25 Now, you know, I'm not going to get into what I

1 believe the defenses are. Pfizer doesn't believe it did that.  
2 It doesn't believe that is (inaudible) off-label marketing but  
3 that's not before your Honor at this point.

4 The reason why this is important is because some of  
5 the discovery that we have asked for and particularly in our  
6 interrogatory responses and in certain documents, the  
7 plaintiffs have redacted certain information which makes it  
8 impossible for us to conduct discovery appropriately. Turning  
9 back to this chart, if you -- In order to determine whether  
10 there was a prescription, because plaintiffs admit, they say  
11 that doctors are allowed to prescribe medicines for off-label  
12 purposes, okay? And the only problem is if Pfizer were to go  
13 into a doctor and encourage him or her to write the prescrip-  
14 tion and the doctor ignored essentially the guidelines and did  
15 something, so the fact of off-label use is not a bad word  
16 because doctors do it all the time. Just manufacturers are not  
17 allowed to do that.

18 Okay, so the issue here is what's an off-label  
19 prescription and what's not an off-label prescription? That's  
20 essentially from, you know, whether they admit that, that's  
21 what I want to know. That's what I want to find out. They  
22 tell me they have \$40 billion worth of damages and I keep  
23 saying, well, show me one. And in order to determine one,  
24 you'd have to know if the person who received the Lipitor  
25 prescription had two or more risk factors. You'd have to know

1 what the LDL level was, 130 to 159, and you'd have to know what  
2 the 10-year cardiac risk history is.

3 So I asked for that information and what they say is  
4 we'll tell you -- We'll give you a list of all Lipitor  
5 prescriptions we've written. Then they say sometimes we'll  
6 give you a list of Lipitor prescriptions we've written and the  
7 names of the doctors who have written them. But I say that  
8 doesn't really help me because you're not looking for oral  
9 Lipitor, you know, ever, and that wouldn't help me understand,  
10 and we asked them literally to (inaudible) these admissions.

11 We've asked them admit that you do not receive LDL  
12 levels in the ordinary course of your business. They admit  
13 that. They admit they don't maintain levels. In fact, which  
14 is frankly a stunning admission, this is Request No. 51 in  
15 their June 6th Amended Supplemental Response and I'm looking  
16 particularly at the Teamsters Local Union but there are --

17 THE COURT: I'm guessing. I don't have anything  
18 June. Is it in this binder? If so, which one is it?

19 MR. JARZYNA: No, your Honor, (inaudible).

20 THE COURT: The thing I have is stamped received June  
21 5th. So I bet I don't have anything that's June 6th.

22 MR. CHEFFO: Okay, well, I'm reading . . .

(Pause.)

23  
24 Hold (inaudible), please.

(Pause.)

25

1 MR. CHEFFO: While Andy is finding it I won't take up  
2 the Court's time. I'll just basically tell you there's three  
3 that I just want to point out.

4 THE COURT: Okay, well, what -- Are we dealing now  
5 with --

6 MR. CHEFFO: We're dealing --

7 THE COURT: Well, hold it. I've got to keep this  
8 straight.

9 MR. CHEFFO: Yes, your Honor.

10 THE COURT: I mean you folks are immersed in this and  
11 I am coming into it cold with a lot of other things going on,  
12 so what we're dealing with now is Motion No. 74, which is  
13 Defendant Pfizer's Motion to Determine Sufficiency of  
14 Plaintiffs' Objections and Responses to Requests for Admission?  
15 Is that what we're dealing with now?

16 MR. CHEFFO: No, we're dealing with the interrogatory  
17 responses.

18 THE COURT: Oh, okay. So that's Motion No. 77, okay.

19 MR. CHEFFO: Yes, your Honor.

20 THE COURT: We're dealing with Motion 77.  
21 Interrogatory answers. Okay.

22 MR. CHEFFO: And this also does touch on the motion  
23 regarding the Rule 26 disclosures, and I'll try and tie that  
24 in --

25 THE COURT: Okay.

1 MR. CHEFFO: -- for your Honor.

2 THE COURT: Give me --

3 MR. CHEFFO: The reason why I'm going to --

4 THE COURT: Give me the interrogatory number that  
5 you're talking about and where I can find it in these papers.

6 MR. CHEFFO: Will do.

7 (Pause.)

8 The . . . Okay, this would be in the First Amended  
9 and Supplemental Responses and Objections and it would be dated  
10 June 6th. Were those --

11 MR. GRYGIEL: We did send Supplemental Answers on  
12 June 6th. Yes, we did.

13 THE COURT: Okay. My guess is I don't have them.

14 MR. CHEFFO: Okay. Well, but the issue is still live  
15 because the supplemental responses don't deal with it.

16 THE COURT: Okay.

17 MR. CHEFFO: So it will be the prior interrogatories.

18 THE COURT: Well, tell me what the interrogatory is.

19 MR. CHEFFO: Yes.

20 THE COURT: Now where can I find the interrogatory?

21 MR. JARZYNA: The interrogatory is Interrogatory No.

22 1 and 2.

23 THE COURT: It would be --

24 MR. JARZYNA: If I might approach?

25 THE COURT: It would be -- Which attachment on this

1 June 5th filing?

2 MR. CHEFFO: (Inaudible).

3 (Pause.)

4 It's our prior -- It's our initial filing.

5 THE COURT: Okay. So it's the requests to admit, the  
6 (inaudible) interrogatories?

7 (Long pause.)

8 MR. CHEFFO: The problem, your Honor, I really do  
9 apologize, we tried to make this easier and I think I made it  
10 harder but we referred back rather than keep giving you the new  
11 exhibits, so I'm just going to give you --

12 THE COURT: Okay, why don't you do this? Read me the  
13 interrogatory.

14 MR. CHEFFO: That's what I'm going to do.

15 THE COURT: Okay.

16 MR. CHEFFO: And I apologize. We'll find this but  
17 what had happened was there was some of the supplementations  
18 corrected things; others didn't.

19 THE COURT: Right.

20 MR. CHEFFO: So the issue here is that state the name  
21 and address of each participant who prescribed Lipitor for an  
22 off-label purpose as defined in the complaint and state the  
23 date of each prescription.

24 THE COURT: Okay, so state the name of any  
25 participant, meaning participant in the fund benefits, who was

1       prescribed Lipitor --

2               MR. JARZYNA: For off-label --

3               THE COURT: -- for off-label purpose and --

4               MR. CHEFFO: As that term is defined in the  
5       complaint.

6               THE COURT: Okay.

7               MR. CHEFFO: So it's very specific.

8               THE COURT: And?

9               MR. CHEFFO: And --

10              THE COURT: And the date of the prescription.

11              MR. CHEFFO: That's right.

12              THE COURT: Okay. And answer?

13              MR. CHEFFO: The answer is some objections and I'll  
14       read it. In addition to the foregoing general objections,  
15       plaintiff objects to the interrogatory as unduly burdensome.  
16       I'm going to skip a few of the objections here. Without  
17       waiving these objections plaintiff will search for and produce  
18       information, if any exists, within its care, custody or control  
19       but reveals the number of participants receiving Lipitor  
20       prescriptions, the number of such prescriptions filled for each  
21       participant, the dates and costs of such prescriptions and the  
22       blood cholesterol levels associated with the prescriptions.

23              And here's what the issue is. We asked for off-label  
24       prescriptions of Lipitor and what I get back is huge volumes of  
25       documents saying here's all the Lipitor we bought.

1           We asked for the names of any participants who fit  
2 these characteristics for off-label use. They come back and  
3 they say we'll produce a copy of the prescription but we won't  
4 tell you the participant name and we won't tell you the doctor  
5 who wrote it. So basically this entire case from 14 months  
6 ago, again I've been asking tell me the author of the  
7 prescription, the doctor, and the participant. We've gone  
8 through HIPAA issues. We have a very extensive protective  
9 order. So the bottom line is, your Honor, they have it because  
10 they have -- they have redacted it.

11           I have -- For example, what I'm showing you here is a  
12 production from one of the funds, EWBTF, which is from 2000 to  
13 2006, and it's a listing of every prescription, Lipitor  
14 prescription and there would be a field that would tell me the  
15 participant information.

16           I mean why is it so important for the participant in-  
17 formation, your Honor? And that's why I was going to the  
18 admissions. Perhaps being a little a convoluted but your Honor  
19 needs to understand that I've asked them do you have informa-  
20 tion about LDL levels for participants? Their answer: We  
21 admit we do not. Admit that your PBM, the pharmacy benefit  
22 manager has the kind of information that I, Pfizer, would need  
23 to determine if the Lipitor prescription was off-label. Their  
24 response: We admit the PBMs don't have that information.

25           So in other words the funds say that the pharmacy

1 benefit managers who control all this, they don't know what  
2 someone's 10-year risk history is. They don't know what the  
3 LDL level is. They don't know what the risk factor. In fact,  
4 in response to one of the admissions they admit that now, 14  
5 months later, none of the 12 funds have even identified, they  
6 have not identified a single participant, a single one who have  
7 used Lipitor for an off-label purpose. We haven't identified a  
8 single doctor who has written an off-label Lipitor prescription  
9 and we have not identified a single prescription that's been  
10 written for off-label.

11 Hence some of the concern that I've had for the last  
12 14 months, which is how could you ever file this lawsuit unless  
13 you actually have some good-faith basis to know that you have  
14 one person who has actually used the product for an off-label  
15 purpose?

16 THE COURT: Okay, I'm going to cut you off there  
17 because I want to recap and make sure I understand what we're  
18 dealing with here. I don't think I ever got a complete copy of  
19 the complaint. No. I think you were going to provide me with  
20 a complete copy of the complaint.

21 MR. CHEFFO: I thought it had been done, your Honor.

22 THE COURT: I don't have it in my file, but I  
23 understand the gist of the lawsuit is the allegation that  
24 Pfizer marketed Lipitor for, quote, "off-label purposes," and  
25 the funds have been improperly or unnecessarily paying for

1 these prescriptions which should not have been written in the  
2 plaintiffs' view. Is that it, Mr. Grygiel?

3 MR. GRYGIEL: That's right, your Honor.

4 THE COURT: Okay. So I understand that the phrase  
5 off-label is in some ways a controversial one in this case.

6 MR. GRYGIEL: Right, because not all off-label  
7 prescriptions, we agree as a matter of basic, positive law, are  
8 improper.

9 THE COURT: Right. Okay.

10 MR. GRYGIEL: And Mr. Cheffo's point, if I might jump  
11 ahead here because I think I can cut to the chase here. We're  
12 having an argument on the merits but, one, I never got a notice  
13 of a deficiency letter about these most recent supplements; and  
14 number two, we could always meet and confer about these things;  
15 and number three, there is another way, your Honor, to look at  
16 this case.

17 THE COURT: Okay. Well, wait, wait, --

18 MR. GRYGIEL: But --

19 THE COURT: I'm trying to understand what the  
20 controversy is.

21 MR. GRYGIEL: Right.

22 THE COURT: And Mr. --

23 MR. GRYGIEL: Mr. Cheffo's argument is we didn't give  
24 you the names --

25 THE COURT: Let me finish.

1 MR. GRYGIEL: I'm sorry.

2 THE COURT: Let me finish. I'm trying to understand.  
3 Mr. Cheffo and his client have served an interrogatory that  
4 requests the names of those people for whom the defendants have  
5 paid benefits for the alleged improper prescriptions.

6 MR. GRYGIEL: Correct.

7 THE COURT: That's what they're trying to find out so  
8 that they can: One, identify the damages; two, dispute, on a  
9 particularized basis, whether or not the prescription was  
10 improper. So am I right, Mr. Cheffo?

11 MR. CHEFFO: Yes, your Honor.

12 THE COURT: Okay. So what's the answer? Now come to  
13 the podium and tell me what the answer is.

14 MR. GRYGIEL: The answer is twofold. Number one, you  
15 don't need the names. The funds, who are in many cases Taft-  
16 Hartley funds with union brothers as their members, have  
17 members who have serious privacy interests in their own medical  
18 records in their own names. I understand Mark's argument, Mr.  
19 Cheffo's argument. It is, well, how do I know that anything  
20 was ever off-label? He said show me one. It's a pretty clever  
21 phrase.

22 The answer to that is that's argument by false  
23 analogy. There's another way to get at it in this case and  
24 that is by Pfizer's own documents. Pfizer said that it was  
25 going to live by the law with two consecutive corporate

1 integrity agreements: No more off-label marketing that they'd  
2 been caught doing with Neurontin.

3 That said, your Honor, and to give you just a little  
4 bit of the background on the other side of the case because  
5 we've heard an awful lot about it now from Pfizer's side, the  
6 market identified for Lipitor users by the guidelines that  
7 became the label indication, that's what demarcates off-label  
8 from on-label, and the guidelines, your Honor, promulgated the  
9 number of 37,000,000 potential users in the appropriate on-  
10 label category for Lipitor.

11 Well, Pfizer says jeez, that's not good enough. We  
12 want to sell more. They're a company. Of course they want to  
13 sell more. How do we expand the market? Now we get somewhere.  
14 In Pfizer's 2004 AK, it projects that it's going to be able to  
15 sell Lipitor to 40 percent of adult Americans, some 79 million  
16 Americans. Well, it's impossible to go from what the  
17 guidelines say, the fundamental prognostication of what the  
18 patient constituents are going to be properly, to that 79  
19 million without having some off-label marketing.

20 You can say well, that's great. That's just  
21 speculation. That's just lawyer talk. But it's not because  
22 even in the extremely narrow category with hundreds of  
23 thousands of pages of documents that Pfizer has recently  
24 produced we get documents such as the following: From Pfizer's  
25 internal memoranda:

1            "To reach our plan of action to goal of \$4 billion  
2            [for Lipitor], each sales representative is responsible  
3            for, 'an increase of two to five new prescriptions a day.'

4            Under that in big boldface:

5            "Do not detail, distribute, copy."

6            Obviously there's a good-faith basis here to believe  
7            numerically and from the documents that are cited in the  
8            complaint, that Pfizer had engaged in off-label marketing. We  
9            didn't just make this up out of thin air and plaintiffs' law  
10           firms like ours don't do that. We have to have a good-faith  
11           basis for it because your Honor, we're in for a penny, in for a  
12           pound. It's all us. We didn't make it up.

13           So that's (inaudible) question: How would you prove  
14           it? It is inconceivable in a case like this that a company  
15           like Pfizer with its 100,000, 115,000 employees all over the  
16           country, all over the world, hasn't done some study of what the  
17           market share is of those parts of its Lipitor universe that are  
18           going for off-label uses.

19           And Mr. Cheffo and I have discussed there's the  
20           individualized granularized way of looking at different patient  
21           constituencies in the different funds and doing some  
22           statistically significant sampling of medical records and  
23           individual plaintiffs which would indeed compel production of  
24           names or some reasonable way of getting at individual records,  
25           doing an extrapolation from that and scientific modeling.

1 That's well-recognized in antitrust cases, in lots of cases  
2 where you've got huge numbers of people involved.

3 The other way you do it is if we get documents from  
4 Pfizer and say, well, our own surveys of our sales representa-  
5 tives, of doctors that we pay money to come to our programs and  
6 talk to us about what's going on, shows that we know that 20  
7 percent of their total billing bucks has come from off-label  
8 uses that are not otherwise medically indicated. At that point  
9 we can (inaudible) and don't need to disclose the names.

10 I haven't gotten those documents yet.

11 THE COURT: Well, I -- It's very interesting to hear  
12 you discuss this, but I am on a level of discovery. And the  
13 discovery rules provide that a party may take discovery of any  
14 matter that's not privileged and that is relevant to any claim  
15 or defense. What the defendants are seeking here is clearly  
16 relevant to the claim.

17 MR. GRYGIEL: I should also point out, your Honor,  
18 that we did say --

19 THE COURT: Well, please, if you don't stop  
20 interrupting me --

21 MR. GRYGIEL: I'm sorry.

22 THE COURT: -- we're going to have a long row to hoe  
23 between now --

24 MR. GRYGIEL: I'm sorry.

25 THE COURT: -- and the end of December.

1 MR. GRYGIEL: I'm sorry.

2 THE COURT: The matter that the defendant is seeking  
3 is clearly discoverable. There's just no question about it.  
4 And the defendant is not required to subscribe to your theory  
5 of your estimation of damages. The defendant -- Just sitting  
6 here I can say I can foresee an argument that although in  
7 theory there might be some over-marketing of Pfizer's Lipitor  
8 that was based on this projected marketing plan, there would be  
9 a question about either whether or to what degree any damages  
10 were incurred by these individual plaintiffs for such activity.

11 You've got to prove, as plaintiffs, not only that  
12 there was overly-aggressive marketing but actually that you  
13 were damaged by it and you were damaged by it in some way that  
14 is more than just speculation. And to the extent that the  
15 defendant is seeking to explore that, whether by your theory or  
16 to refute it by taking discovery to prove that your theory has  
17 no factual basis if you go on a more modeled, as you say,  
18 manner, that's still within the scope of discovery.

19 Now there are a lot of known knowns here, or at least  
20 known to the funds. The funds know every participant. They  
21 know that. It's a large group of people but they know it.  
22 It's a known known, as Donald Rumsfeld would say.

23 They also know or can find out those participants who  
24 received benefits for prescriptions. That's a known known.  
25 They can then narrow it down to those who received

1 prescriptions for Lipitor. Now it gets a little more  
2 complicated when you try to narrow it down to off-label  
3 because, as I discussed earlier, my understanding is that off-  
4 label is a phrase that needs some definition and further  
5 complicated by the fact that not every, quote, "off-label," the  
6 parties, concede, usage of a particular drug is necessarily an  
7 improper usage of that particular drug and it's really only  
8 improper usages that I understand the plaintiffs are seeking  
9 any remedy for.

10 So, you know, there's a lot there but there's a lot  
11 of potential there. I certainly think that this is an answer  
12 that can be made and certainly one that is going to be, I fore-  
13 see, really a substantial part of any discussion about damages.  
14 Whether or not the plaintiff thinks that this is the way they  
15 want to prove them or not, it's going to be a part of the  
16 discussion of damages because the defendant is going to  
17 approach it perhaps in that way. So it is certainly  
18 discoverable.

19 Now the only question I have is how you are going to  
20 approach preparing the answer to that question. That's where I  
21 think some conversations can be had about how that information  
22 is going to be put together by the plaintiff and how much --  
23 how long it is going to take.

24 MR. GRYGIEL: Your Honor, if I may, I apologize again  
25 for interrupting. This is what I wanted to say: Is I did not

1 issue a flat refusal on the names and I recognize clearly the  
2 position your Honor has articulated because Mr. Cheffo has  
3 articulated to me more than once, and I understand it  
4 perfectly. And at least as to a couple of these funds with  
5 whom we've had discussions, I know we're going to be able to  
6 produce names. And I've told Mr. Cheffo that as to some of  
7 these other funds discussions are still ongoing.

8 I mean truly, your Honor, producing the names is, you  
9 know, it's administratively, as you know from the documents  
10 that Mr. Cheffo was describing, a matter of just unredacting on  
11 a live e-mail basis or a live computer basis the names. We can  
12 do that. I just needed permission to do it and so far I think  
13 two plans have said go ahead, give them the names, we've got a  
14 protective order, that's okay.

15 MR. CHEFFO: Can I just --

16 THE COURT: Well --

17 MR. CHEFFO: I'm sorry, your Honor.

18 THE COURT: Go ahead, Mr. Cheffo.

19 MR. CHEFFO: The names are one thing and, you know,

20 I'm --

21 THE COURT: Yes, the names are the start.

22 MR. CHEFFO: -- -- (inaudible, multiple voices).

23 That's just, you know, I mean the question is tell me the off-  
24 label. And just to frame this, let's put aside the 40, 50  
25 billion dollars. One of the documents -- And I'll approach,

1 your Honor, this is from -- Let's see, this is (inaudible) 1,  
2 it's a -- Oh, there it is. Thank you. Do you have an extra  
3 copy?

4 MR. JARZYNA: (Inaudible), your Honor.

5 MR. CHEFFO: I certainly won't belabor this point,  
6 your Honor, but this is the, I guess to some extent, it what  
7 the fund paid for. It's pretty easy to see, you know,  
8 (inaudible) the total number of prescriptions for one of the  
9 funds during the period. It actually goes beyond the period,  
10 and how much the plan participants paid for it. I guess the  
11 co-pay. And that's it. But that's everything. So in other  
12 words we paid 180-some-odd thousand dollars for Lipitor.

13 Now the question becomes how much of that is, you  
14 know, for off-label?

15 THE COURT: Some of these Lipitor prescriptions would  
16 by anybody's definition be completely proper.

17 MR. CHEFFO: Exactly.

18 THE COURT: So we have to find some way that the  
19 plaintiff is contending the basis for distinguishing between  
20 those who were proper and those who weren't proper. And there  
21 has to be some way that that's going to be identified in some  
22 non-speculative way and I just don't think you can, at least  
23 for discovery purposes, I'd be -- and I certainly think it  
24 would be really iffy at trial, even, to just say we're going to  
25 take it all from Pfizer's documents.

1           You've got to talk about what your client incurred,  
2 not just what Pfizer hoped the universe of purchasers would  
3 ultimately pay it.

4           MR. GRYGIEL: Your Honor, I believe with respect,  
5 that there are statistically valid models that you would be  
6 able to use that would be able to take Pfizer documents, do a  
7 comparability in the matter of economic standpoint between  
8 those universes that Pfizer measured, because I'm sure they  
9 did. We haven't gotten it yet. I believe that will be in the  
10 electronic discovery. I sure hope it is.

11           MR. CHEFFO: But --

12           MR. GRYGIEL: And what we have here within our own  
13 plan and say comparable, not comparable, or not enough to go  
14 on. That's a question of expert testimony which I believe is  
15 down the road --

16           THE COURT: Oh, no, no, no.

17           MR. GRYGIEL: -- as to -- (inaudible, multiple  
18 voices).

19           MR. CHEFFO: This is apples and oranges.

20           THE COURT: We've got to have facts. You've got to  
21 have facts, and the underlying fact is that the plaintiff is  
22 claiming billions of dollars were paid unnecessarily by the  
23 funds for improper Lipitor prescriptions. So you've got to  
24 break out in some way what prescriptions you believe were  
25 improper. Actual prescriptions, not theoretical prescriptions

1 for some theoretically-modeled universe. But actual  
2 prescriptions that you believe were improperly prescribed for  
3 which your clients improperly paid.

4 The defendants have a right to get some concrete on  
5 this. This is not -- This isn't abstraction. This isn't  
6 speculation. This is concrete claimed damages. We're going to  
7 have some concrete information to refute it or support it,  
8 whatever it does. But we'll find a way to get at what  
9 specificity. And you know, I'm hearing you that it's a big  
10 task, but I think you might -- You've got to find some ways  
11 that you think you can approach it because I'm going to compel  
12 it and that's going to be the bottom line. You find a reason-  
13 able way to do it.

14 And maybe what you might want to do is start with one  
15 fund that you think -- You identify, you being the plaintiff --  
16 is one that is, pick your criteria, either the easiest to do  
17 because they have the best records, or most likely to prove to  
18 have the greatest amount of damages or the ones you have the  
19 best relationship with. You pick it, but that might be one way  
20 of approaching it.

21 But I think the question is one that, though  
22 difficult of answer, is not unduly burdensome in light of what  
23 the claimed damages are here, the nature of the claim. The  
24 only reason it becomes difficult is because there are so many  
25 plaintiffs with so many people. If there was one fund you

1 wouldn't have -- I wouldn't have a problem compelling them to  
2 answer that question. So all we're doing is dealing with the  
3 fact that how many, 20 funds have joined into this action. So  
4 let's pick one and start with that.

5 MR. GRYGIEL: We can do that, your Honor.

6 THE COURT: Mr. Cheffo, does that --

7 MR. CHEFFO: I'm going to be guided by your Honor. I  
8 think we have to start somewhere, you know, and that makes  
9 sense. I think if we start and plaintiffs, you know, identify  
10 the information and the criteria that they believe that there  
11 are certain off-label uses, I mean we know for example that  
12 this fund, yes, I mean it's 1800 prescriptions and frankly,  
13 it's not -- That's not a huge amount even if you start with the  
14 80, Lipitor 80, is only 30 prescriptions, you know? So if they  
15 started with a fund and they basically go, they identify, they  
16 say okay, here's a person who has the two or more risk factors  
17 who has this particular LDL level and had a cardiac risk, you  
18 know, we think this is off-label. And --

19 THE COURT: Not just off-label, but improperly off-  
20 label.

21 MR. CHEFFO: Improperly off-label.

22 THE COURT: I mean that's really the bottom line  
23 question because off-label is just a subset. Improperly and  
24 actionably off-label is really what the defendant wants to  
25 know. Yes?

1 MR. CHEFFO: Exactly right, your Honor, because if  
2 someone had taken, for example, Zocor and got switched because  
3 they were having some muscle pain, they might fall within this  
4 category but the plaintiffs presumably wouldn't say that that  
5 was improper because it was a chemical that reduced their LDL.  
6 It has to be, as you say, something consistent with the  
7 allegations in the claim, that it's improper and I think you  
8 articulated it better than I did, your Honor.

9 THE COURT: So start with us, you know, a group, one  
10 fund, and answer it with respect to that one fund and after  
11 that is done, maybe you can have further conversations between  
12 counsel about how you want to proceed. Because I think that  
13 will tell you something about -- It will put some more  
14 specificity onto the issue of what the plaintiff is considering  
15 to be the improperly off-label use and prescription that will  
16 help, I think, move things forward a lot better.

17 So with that, I guess the question is we've got to  
18 get some time frame on this. What do you think?

19 MR. GRYGIEL: I believe, your Honor, I'll be in a  
20 position to identify at least one fund for which we can give  
21 that specificity of information by Tuesday of next week.

22 THE COURT: All right, and then when will the infor-  
23 mation be forthcoming?

24 MR. GRYGIEL: I would think quite soon thereafter,  
25 within --

1 THE COURT: Great.

2 MR. GRYGIEL: -- probably by Friday of that week.

3 THE COURT: Well, then that's good.

4 MR. GRYGIEL: I haven't confirmed that, but that's my  
5 good-faith estimate and thus far I think I've been pretty close  
6 on everything I've told Mr. Cheffo.

7 THE COURT: Well, that's good. I mean then you -- In  
8 a big case like this, you have to like break it down into  
9 pieces that are most likely to give you meaningful information  
10 about how you move forward.

11 Mr. Cheffo?

12 MR. CHEFFO: Well, I think that's reasonable. I  
13 think what we might do is, you know, just to make sure we're  
14 all on the same page, is if he had, you know, (inaudible) to  
15 suggest maybe some kind of compliance date and then we can, if  
16 it turns out that the information that Mr. Grygiel provides is  
17 appropriate then we can, you know, . . .

18 THE COURT: All right, what's the number of your  
19 interrogatory? Identify the interrogatory that you're seeking  
20 a response to.

21 MR. CHEFFO: Well, it's really, I guess, your Honor,  
22 it goes to 1, 2, 3 and 4, but the one I read to you, the one I  
23 read to you was No. 2, Interrogatory No. 2.

24 THE COURT: Interrogatory 2 of?

25 MR. CHEFFO: Of --

1 THE COURT: Defendant's --

2 MR. CHEFFO: -- defendant's first interrogatories to  
3 plaintiff Southern Illinois Laborers.

4 THE COURT: All right.

5 MR. CHEFFO: That interrogatory, and --

6 THE COURT: Was that interrogatory sent basically to  
7 all of the funds?

8 MR. CHEFFO: Yes.

9 THE COURT: Okay. So the plaintiff will provide  
10 answers to Interrogatory 2 of defendant's first set of inter-  
11 rogatories with respect to one plaintiff fund.

12 MR. CHEFFO: And can I just, because I think, your  
13 Honor, that's fine. But I think that actually 1, 2, 3 and 4,  
14 when you put them together, interrogatories, they capture the  
15 information that you articulated. In other words, 2 says  
16 identify each prescription of Lipitor for an off-label purpose  
17 as defined in the complaint for which you paid or sought  
18 reimbursement, so really what we're trying to do is put  
19 together the prescription, the participant, and the doctor who  
20 wrote it because, you know, that's the information that I think  
21 we would ultimately need in order to pursue these criteria.

22 THE COURT: Mr. Grygiel?

23 MR. GRYGIEL: Well, as I look at -- To get the names,  
24 I think, at least as to one fund is going to be relatively  
25 prompt and consistent with --

1 THE COURT: Not just names.

2 MR. GRYGIEL: Right.

3 THE COURT: We're talking not just names. We're  
4 talking --

5 MR. GRYGIEL: That's what I've been talking --

6 THE COURT: -- about prescriptions.

7 MR. GRYGIEL: -- a moment ago.

8 THE COURT: Well, I'm talking about answering the  
9 interrogatories.

10 MR. GRYGIEL: I understand.

11 THE COURT: Not just names. We want the names, we  
12 want the prescriptions that are allegedly for the improper off-  
13 label usage. That's what we want.

14 MR. GRYGIEL: And that obviously entails getting  
15 certain medical records that are consistent with the  
16 prescriptions that got written, and that gets a little bit more  
17 complicated because then you're not talking --

18 THE COURT: That's why I was surprised that you  
19 thought you were going to be able to do it by next week. We've  
20 got to get the plaintiff's name, I mean you've got to get the  
21 names. We want -- Just get one set of things that you think  
22 were wrongly done, one fund, so we have it out there. I don't  
23 see why that should be so hard.

24 MR. GRYGIEL: Understood, your Honor.

25 THE COURT: I mean I understand it will take you a

1 little while and it's going to take some analysis but in the  
2 end of the day this is what you're going to have to do to prove  
3 your case. I mean you're not going to be able to prove this  
4 case, I don't think, by simply going back and saying Pfizer had  
5 a scheme.

6 MR. GRYGIEL: I agree with that, your Honor.

7 THE COURT: And Pfizer had a hope, and Pfizer had an  
8 intention and we were the targets of that intention, ergo, give  
9 us \$17 billion. I just don't think that's going to work. I  
10 think you're going to have to demonstrate that there were real  
11 people who really ended up getting prescriptions for off-label  
12 and improperly off-label purposes of Lipitor for which these  
13 funds paid. That's what you're going to need to do to prove  
14 your case and you might as well start with one subset of these  
15 people and get the specific information out there about them  
16 and tell the defendants why you think they're improper.

17 Maybe from that some projections can be made, or  
18 maybe not. But the first is you start with specifics. You  
19 don't start with grand schemes and aspirations that may or may  
20 not ever have materialized. You've got to get down with some  
21 specifics.

22 So what we're talking about is answering Inter-  
23 rogatories, is it 2?

24 MR. CHEFFO: 1, 2, 3, 4.

25 THE COURT: Okay.

(Pause.)

THE COURT: Well, what you're really going for is 3. If you had 3, you'd have everything that's in 1 and 2 except the address.

MR. CHEFFO: I think your Honor is probably correct in (inaudible) each description, that's fine.

THE COURT: You'd have the doctor, you'd have the date, you'd have everything.

MR. CHEFFO: Right. To the extent that it has the. . . (Pause.)

THE COURT: So do that for one fund. Okay, we have to take a break because we have a criminal case and I have to address that, so you can stay or you can leave and come back. We'll just take a break in the civil case. But think about that and think about how that's going to be addressed by the plaintiffs.

(Break during which the Court heard unrelated matters.)

THE CLERK: 06-C-1818, Southern Illinois Laborers and Employers Health and Welfare Fund v. Pfizer.

THE COURT: All right. Well, the same people are here who were here before so let's resume where we were.

MR. CHEFFO: I was going to say as happens, I think, all too often, when you give us a few minutes to talk we are able to narrow some of the issues. So --

THE COURT: Excellent, doesn't happen too often for

1 me, my taste. (Laughter.)

2 MR. CHEFFO: But and again, Mr. Grygiel will confirm  
3 this: I think he's indicated pursuant to the Court's order  
4 that he's going to contact one of the funds and I think as much  
5 as, you know, I would like to have a date certain I also  
6 understand that he needs to talk to his client to get some more  
7 granularity about how long that's going to take, so I think  
8 what Mr. Grygiel has committed to do within the, you know, the  
9 next few days is to talk to one of the funds and for that fund  
10 identify how long it will take to identify, you know, each  
11 Lipitor prescription that was written for allegedly improper  
12 off-label purpose that it paid for.

13 And then from that point perhaps we can set a target  
14 date in a few weeks based on the Court's convenience and  
15 calendar to come back and if we need to find out where we are.  
16 Is that fair?

17 MR. GRYGIEL: That's fine, your Honor.

18 THE COURT: I think that makes sense. I'm just  
19 trying to get the order down and what I think needs to happen  
20 is let's set a date for you to contact counsel again with the  
21 further status on the providing of -- what fund will be  
22 providing the information to start with.

23 MR. GRYGIEL: On Monday.

24 THE COURT: All right. All right.

25 MR. GRYGIEL: I should have an answer by then. I

1 hope to do it sooner but I have mediation Friday so let's say  
2 Monday.

3 THE COURT: Okay. Well then, and an estimate of how  
4 long it would take to provide that information. So read it  
5 again, Mr. Cheffo?

6 MR. CHEFFO: Yes, your Honor. Mr. Grygiel will  
7 provide a date by which one fund will identify each Lipitor  
8 prescription written for an allegedly improper off-label  
9 purpose that it paid for on behalf of its participants.

10 THE COURT: Okay. Okay, that's a good start. And  
11 then we'll get a handle on how hard it's going to be to do  
12 this.

13 (Pause.)

14 So that's going to be by Monday is the 18th. Yes.  
15 By 6-18. All right. All right, and do that in writing, you  
16 know, confirm it in writing.

17 MR. GRYGIEL: Yes, your Honor.

18 THE COURT: In writing. All right, well, that's a  
19 good start.

20 MR. CHEFFO: And with that there's really two, I  
21 think, issues. One almost dovetails so I'll -- Let me deal  
22 with them. I think they're both discrete. I may have over-  
23 stated in my joy for having us reached agreement, 11 of the 12  
24 funds we're still good with in terms of interrogatories and  
25 documents and admissions. And forgive me, your Honor, I should

1 have advised you of this earlier. There is one fund, the  
2 Sidney Hillman Fund of Rochester and as it turns out, that fund  
3 was one of the added funds in December, and they really -- And  
4 I think Mr. Grygiel may speak to this -- they really have not  
5 complied with discovery in any respect and even in the most  
6 recent supplement, as I indicated that was, I think, adequate  
7 that the other eight funds did, the Sidney Hillman Fund really  
8 has not done anything. So everything is ripe, essentially, as  
9 to their documents, interrogatories and admissions. And I  
10 don't know what the position or where Sidney Hillman is on  
11 that.

12 MR. GRYGIEL: Well, your Honor, I spoke with Mr.  
13 Cheffo about this and I spoke with him I think it was two weeks  
14 ago about the possibility to moving to dismiss Sidney Hillman.  
15 The case has a bunch of plaintiffs and we already have a New  
16 York fund. I thought frankly two New York funds was  
17 unnecessary. One will streamline this litigation. I asked Mr.  
18 Cheffo what his position was on dismissal. I understand from  
19 our hallway conversation that he's probably going to oppose  
20 that, an easy dismissal if I can frame it thusly, and therefore  
21 I'm more likely now to have to move for a dismissal of that  
22 case.1

23 THE COURT: Um-hum.

24 MR. GRYGIEL: And they have not -- They did comply in  
25 the beginning. They did produce some discovery, your Honor. I

1 don't think it's accurate to say that there's nothing,  
2 responded to nothing, but they did not supplement. That is  
3 true.

4 MR. CHEFFO: It's fair. I may have overstated that.

5 MR. GRYGIEL: That's fine.

6 MR. CHEFFO: I mean there were nonsubstantive  
7 responses.

8 THE COURT: Okay. Well, let's get a process here for  
9 bringing this issue to a head. I mean we can do it either one  
10 of two ways. What I'm thinking of is directing that plaintiff  
11 individually to file a response to the plaintiffs' motions to  
12 compel on its behalf by X date. And then that way either there  
13 will have to be some argument as to why its responses are  
14 compliant pursuant to the requirements of the Federal Rules, or  
15 they're going to have to make a decision that they're going to  
16 seek to be taken out of this case one way or the other  
17 voluntarily.

18 I assume what you're anticipating is if they decide  
19 that they just, at this point, don't want to follow along with  
20 this particular case they're going to move to voluntarily  
21 dismiss without prejudice. And that's going to be --

22 MR. GRYGIEL: Well, there's already been an answer  
23 filed.

24 MR. CHEFFO: Well, there's two things. It's not that  
25 we're, you know, just to -- I don't think there's been a

1 suggestion that we're being unduly tough here, but the Sidney  
2 Hillman Fund is one of the six initial funds that filed its own  
3 individual action back in March of 2006 along with the Southern  
4 Illinois case. It was one of the five that dismissed without  
5 prejudice pursuant to Rule 41, so they already did that.

6 And then it moved, in December, to get back into this  
7 case and add itself into the case so hence, you know, that's  
8 where, and then we served discovery and they basically served  
9 some responses but I don't think complied with the Rules, and  
10 we're now, you know, six or seven months later. So they've  
11 already taken a without prejudice voluntary dismissal. This,  
12 you know, our position would be it would have to be with  
13 prejudice and we'd have to consider, my client would have to  
14 consider whether they would pursue costs.

15 THE COURT: Well, what I have here is discovery.

16 MR. CHEFFO: Um-hum.

17 THE COURT: And if you're telling me that the Sidney  
18 Hillman Fund of Rochester, New York has not, in your view, even  
19 come up to where the rest of the plaintiff funds are, then I'm  
20 going to direct the Sidney Hillman Fund of Rochester, New York,  
21 to file by July 6th its response to the plaintiffs' motion to  
22 compel, specifically explaining why its responses to the  
23 plaintiffs' discovery comply with the Federal Rules of Civil  
24 Procedure. And we'll focus on individually what those are.

25 MR. CHEFFO: Okay, your Honor, thank you. And -- I'm

1       sorry, were you finished, your Honor?

2               THE COURT:   Yes.

3               MR. CHEFFO:   And the last thing, this dovetails, I  
4       think a similar order (inaudible) but I just want to flag it so  
5       when we come back in a few weeks it won't be new to the Court,  
6       but with respect to our Rule 26 motion, our real issue was, I  
7       think, dovetails with this issue of specificity with respect to  
8       the individual providers.  In other words, what for three of  
9       the funds the plaintiffs have now supplemented and told us is  
10      they've paid \$183,000 so that's their calculation, with respect  
11      to everyone else they basically added up Pfizer's, you know,  
12      full gross sales for Lipitor for the four years.

13              I'm most concerned about the fact that they claim to  
14      be asking the 40, you know, billion dollars.  What I ultimately  
15      think, and I do recognized based on the Court's ruling, that  
16      this may now take a little bit of time, what I think what would  
17      be appropriate in their damage calculation as they identify for  
18      each fund the actual off-label improper Lipitor prescriptions  
19      that they attach, you know, a numeric value to that for funds  
20      specific, and supplement their Rule 26.  I think it's not going  
21      to be burdensome.  It's probably, you know, do it on a  
22      calculator --

23              THE COURT:   Well --

24              MR. CHEFFO:   -- if you understand what I'm asking.

25              THE COURT:   Well, you know, what Rule 26 requires a

1 party to do is to perform its damage calculation.

2 MR. CHEFFO: Okay.

3 THE COURT: So the way that Mr. Grygiel was  
4 suggesting the plaintiffs is going to approach damages is  
5 different from the way you're approaching damages. So you  
6 can't make them spell out calculations according to your  
7 theory. If they have enunciated their theory, that's their  
8 theory.

9 MR. CHEFFO: Okay.

10 THE COURT: Your further requests are in response to  
11 your interrogatories and you can calculate it up. But what the  
12 Rule 26 disclosures are good for is the fact that that's their  
13 damage calculation. They can't switch in midstream unless they  
14 come in and change their Rule 26.(a)(1) disclosure. Do you see  
15 what I'm saying?

16 MR. CHEFFO: I see exactly, your Honor, and I  
17 certainly will abide by that ruling. I think that makes sense  
18 to me.

19 THE COURT: I mean that's basically how I read Rule  
20 26 in conjunction with Rule 37. You put your theory out there.  
21 You put your calculation out there. And if later on it turns  
22 out that your calculation has holes in it you can't switch over  
23 to some other theory without getting some, you know,  
24 supplementing your disclosure to say okay now, I'm changing my  
25 theory somewhat, I'm going to a more particularized basis.

1           And putting a little meat on it in this context, what  
2 I heard Mr. Grygiel say is that they think that they can prove  
3 damages by showing to what proportion of increased profits  
4 based on Lipitor the Pfizer achieved based on this estimate by  
5 expert calculation of what percentage of those profits were  
6 based on off-labelling in a modeling way, so to speak. Is that  
7 right, Mr. Grygiel?

8           MR. GRYGIEL: That's correct, your Honor.

9           THE COURT: Okay. What the defendants are saying is  
10 we don't think that's the right approach. We think you have to  
11 show that this fund, Sidney Hillman Fund of New York, actually  
12 paid \$20,000 for Lipitor and that \$10,000 of it was, by your  
13 definition, improper. Well, you can't switch horses in the  
14 middle of the stream and go over with the plaintiffs unless you  
15 come back with a model that sets out the information that would  
16 be responsive had you identified that theory in the beginning.

17           MR. GRYGIEL: What we've done, your Honor, is  
18 identify fund-specific damages for a couple of the funds, three  
19 in particular with numbers that show how much the funds paid,  
20 the member and the plan, and we've got some numbers for that.  
21 And there are a couple where neither Mr. Cheffo or I are  
22 immediately in a position to say here's exactly the amount of  
23 money that was spent on Lipitor because it's an aggregate  
24 amount in these documents that number thousands of pages. You  
25 need a highlighter, a calculator and a lot of time.

1 But I just want to be clear that within the scope of  
2 the complaint we have a claim for unjust enrichment, and our  
3 theory is that because revenues from off-label sales of Lipitor  
4 are commingled with sales of properly-prescribed Lipitor, that  
5 it's not our burden to have to essentially disassociate that  
6 and when we showed the total amount of Lipitor sales that we  
7 are entitled to claim that is the total number of damages. I  
8 have a feeling that with expert testimony and further develop-  
9 ment in this case, there's going to be some further fine  
10 reticulation of how that works. But all I'm saying, your  
11 Honor, is that yes, I agree with you.

12 THE COURT: Well, what I'm -- I want to make myself  
13 clear. I'm not making any rulings. I am expressing the view  
14 that Rule 26.(a)(1) requires full disclosure of your damage  
15 calculations. So you know, you can't change that theory and  
16 that calculation method without some further  
17 supplementation --

18 MR. GRYGIEL: Yes.

19 THE COURT: -- of your Rule 26.(a)(1) disclosures  
20 which has to be reasonable, according to the Rule, and if it's  
21 not timely and it's not reasonable it can be excluded by the  
22 District Judge. So the course that avoids an unfortunate  
23 motion in limine pursuant to Rule 37 at the trial level is one  
24 that makes sure that there has been full timely disclosure  
25 under Rule 26.(a)(1). The careful party makes sure that its

1 disclosures keep up with whatever the development of its  
2 evidence and theory reflects to make sure that there's no  
3 preclusion under Rule 37 at trial. That's what I'm saying.

4 And if you think that there are further answers to  
5 interrogatories that need to be forthcoming, then here's the  
6 place. But at this point I think that I'm hoping you're going  
7 to say that I can put all these big fat binders away and that  
8 anything else that comes to me will come to me fresh with,  
9 perhaps, one exhibit or two exhibits attached to it. Is  
10 that --

11 MR. CHEFFO: I think that's our mutual goal.

12 MR. GRYGIEL: It is our mutual goal, your Honor.

13 THE COURT: Excellent, okay. So let's go back over  
14 the rulings today. What I'm going to say is that motion  
15 hearing held on all of the motions. Except to the extent  
16 previously ruled upon or ruled upon today, the motions are moot  
17 as indicated by counsel on the record.

18 MR. CHEFFO: Um-hum.

19 THE COURT: And what's going to happen here, what the  
20 order is going to say is that, let's see. We had the earlier  
21 statement that by the -- You're going to give the status on the  
22 document production. You have that?

23 MR. CHEFFO: Um-hum.

24 THE COURT: The 26th, all right. And then  
25 additionally, Nicole, while you were out there was a ruling

1 that by the 18th, June 18th, the plaintiff will provide in  
2 writing the date by which the plaintiff will identify each  
3 prescription for Lipitor written for allegedly improper purpose  
4 for which -- You read it, Mr. Cheffo.

5 MR. CHEFFO: Yes, yes, your Honor.

6 THE COURT: You did a better job.

7 MR. CHEFFO: No. For one fund plaintiff will  
8 identify each Lipitor prescription written for an allegedly  
9 improper off-label purpose that it paid for on behalf of its  
10 participants.

11 THE COURT: That's it. And also plaintiff, Sidney  
12 Hillman Fund of Rochester, New York shall file by July 6th its  
13 response to defendant's motions to compel setting out why the  
14 Sidney Hillman Fund of Rochester, New York, believes that its  
15 responses comply with its obligations under the Federal Rules  
16 of Civil Procedure.

17 All right, I think that is it for today.

18 MR. GRYGIEL: Two housekeeping matters if I may, your  
19 Honor.

20 THE COURT: All right.

21 MR. GRYGIEL: One, I'm embarrassed, chagrinned that I  
22 filed something with this Court that the Court didn't receive.  
23 I had a copy to give you here and it disappeared in a flurry.  
24 It wouldn't be in the form your Honor wants anyway. We'll  
25 resubmit that.

1 THE COURT: Okay.

2 MR. GRYGIEL: Number two, Mr. Cheffo explained to me  
3 that he did serve accordingly the document that I said I didn't  
4 get, so I'm not casting any aspersions, I just wasn't on the  
5 service list is what happened so I hadn't seen that.

6 And the third thing is your Honor said that you did  
7 not receive a copy of the complaint.

8 THE COURT: I don't think we did.

9 MR. GRYGIEL: Sometimes I feel like I'm dealing with  
10 one of my five kids when I talk to people who work with me. I  
11 hear things are coming and they're not. I can certainly take  
12 care of that, your Honor, tomorrow.

13 THE COURT: Well, what does the docket look like in  
14 terms of your being on the docket there? You know, that's -- I  
15 think the problem here is if you want to get notice you've got  
16 to be actually of record on our --

17 MR. CHEFFO: E-filing.

18 THE COURT: -- e-filing and you're not. It doesn't  
19 look like you are.

20 Let's see here.

21 MR. CHEFFO: Sid Liebesman from his firm is but he  
22 probably needs to get himself on it.

23 MR. GRYGIEL: That would be helpful.

24 THE COURT: Yes. I mean you absolutely have to or  
25 you won't get it. Do you have a pro hac vice application or

1 are you member of the Bar of the Northern District?

2 MR. GRYGIEL: I understand that my pro hac vice  
3 application has been filed and granted.

4 THE COURT: Well, let's see. It's not on the docket  
5 so before you leave you'll want to go to the 20th floor and  
6 figure out what's going on.

7 MR. GRYGIEL: I will.

8 THE COURT: And make sure that you get onto the  
9 docket on the 20th floor. Absolutely critical.

10 And so your local counsel here is who?

11 MR. GRYGIEL: George Bellas at the Clifford Law Firm.

12 THE COURT: Okay. Just make sure that any courtesy  
13 copies get to my courtroom deputy at 1808. Now it used to be  
14 that you had to file an original and one copy on the 20th  
15 floor. Now of course there's electronic filing and we don't --  
16 We still require a judge's paper copy but in terms of motions  
17 that are coming to me, don't file it on the 20th floor. File  
18 it with -- Bring it to my courtroom deputy because filings that  
19 go to the 20th floor, even though they're intended for the  
20 Magistrate Judge, very often end up in the District Judges'  
21 chambers and if they deal with discovery they can be set aside  
22 or even discarded because that's what they refer the discovery  
23 to the Magistrate Judge for. So they wouldn't get into the  
24 filings.

25 So let's do that, but I would like a complete copy of

1 the complaint.

2 MR. GRYGIEL: Yes, your Honor.

3 THE COURT: To be brought over to my courtroom deputy  
4 with the exhibits and all.

5 So with that I think it would be a good idea to set a  
6 further status in this matter. The last thing that's going to  
7 happen is the Sidney Hillman Fund is going to tell us what it's  
8 going to do on the 6th of July, so I think a status anytime  
9 after the 12th would work for me. I know you're coming from  
10 out of town, Mr. Grygiel, so let's see. And people have  
11 vacations and so on. I'm thinking that perhaps the following  
12 week would work, perhaps Thursday of the following week?

13 MR. GRYGIEL: What's that date, your Honor?

14 THE COURT: The 19th?

15 MR. GRYGIEL: Thursday, July 19th?

16 THE COURT: Thursday, July 19th at, if you're coming  
17 from out of town we can make it a little later. I will have  
18 criminal duty, that's the risk is the possibility that there  
19 will be -- You'll have to wait for a few minutes. But I would  
20 set it at ten so you can fly in that morning and fly out again.  
21 Ten o'clock on the 19th.

22 MR. GRYGIEL: That's fine, your Honor.

23 THE COURT: So the 19th at ten a.m. All right.

24 Is there anything else for today?

25 MR. CHEFFO: (Inaudible) than our question introduced

1 earlier, that's (inaudible) which is summer associates at  
2 Skadden (inaudible) sitting there but thank you very much for  
3 handling a large amount of paper and issues in a very short  
4 time, your Honor.

5 THE COURT: Well, you narrowed it down considerably  
6 so this binder is yours, Mr. Cheffo.

7 MR. CHEFFO: Oh, yes.


8 THE COURT: I'm going to take these two exhibits that  
9 you gave me and put them with the rest of this, and I'll wish  
10 everyone a nice 4th of July holiday. Is there anything else?

11 MR. JARZYNA: Thank you, your Honor.

12 MR. GRYGIEL: Thank you.

13 (Hearing adjourned.)

I, RIKI SCHATELL, certify that the foregoing is a  
correct transcript from the record of proceedings in the  
above-entitled matter.

  
Riki Schatell

June 18, 2007  
Date

# **EXHIBIT I**

**UNITED STATES DISTRICT COURT  
FOR THE Northern District of Illinois – CM/ECF LIVE, Ver 3.0  
Eastern Division**

Southern Illinois Laborers' and Employers Health and  
Welfare Fund, et al.

Plaintiff,

v.

Case No.:  
1:06-cv-01818  
Honorable John W.  
Darrah

Pfizer Inc.

Defendant.

---

**NOTIFICATION OF DOCKET ENTRY**

This docket entry was made by the Clerk on Thursday, June 14, 2007:

MINUTE entry before Judge Geraldine Soat Brown : Motion hearing held. Except to the extent previously ruled upon or ruled upon today, all pending motions to compel [68], [72], [74], and [77] are moot as indicated by counsel on the record. No later than 07/06/07, plaintiffs' counsel and defendant's counsel shall exchange letters on the status of document production, including an anticipated schedule for completing production. By 06/18/07, plaintiff will identify in writing, the name of one plaintiff fund that will identify each Lipitor prescription written for an allegedly improper off label purpose that they paid for on behalf of its participants. By 07/06/07 plaintiff Sidney Hillman Health Center of Rochester shall file its response to defendant's motions to compel setting out why it believes that its responses comply with its obligations under the Federal Rules of Civil Procedure. Status hearing set for 07/19/07 at 10:00 a.m. Notice mailed by judge's staff (ntf, )

**ATTENTION:** This notice is being sent pursuant to Rule 77(d) of the Federal Rules of Civil Procedure or Rule 49(c) of the Federal Rules of Criminal Procedure. It was generated by CM/ECF, the automated docketing system used to maintain the civil and criminal dockets of this District. If a minute order or other document is enclosed, please refer to it for additional information.

For scheduled events, motion practices, recent opinions and other information, visit our web site at [www.ilnd.uscourts.gov](http://www.ilnd.uscourts.gov).

# **EXHIBIT J**

**UNITED STATES DISTRICT COURT  
FOR THE Northern District of Illinois – CM/ECF LIVE, Ver 3.0  
Eastern Division**

Southern Illinois Laborers' and Employers Health and  
Welfare Fund, et al.

Plaintiff,

v.

Case No.:  
1:06-cv-01818  
Honorable John W.  
Darrah

Pfizer Inc.

Defendant.

---

**NOTIFICATION OF DOCKET ENTRY**

This docket entry was made by the Clerk on Tuesday, August 28, 2007:

MINUTE entry before Judge Geraldine Soat Brown : Motion hearing held. Defendant's motion to compel [101] is granted as follows; Plaintiffs shall serve a formal answer to defendant's interrogatory 3 as to Plumbers & Pipefitters Local Union 630 Welfare Trust Fund no later than 08/31/07. The motion is granted further in that the plaintiffs shall serve a formal response to defendant's interrogatory 3 with respect to each of the remaining plaintiffs; the date for serving that answer shall be the subject of a meet and confer between counsel, if no agreement is reached, the date will be determined by the court. Status hearing previously set for 08/30/07 at 10:00 a.m. is stricken and reset to 09/04/07 at 9:30 a.m. following the motion hearing before the District Judge. Notice mailed by judge's staff (ntf, )

**ATTENTION:** This notice is being sent pursuant to Rule 77(d) of the Federal Rules of Civil Procedure or Rule 49(c) of the Federal Rules of Criminal Procedure. It was generated by CM/ECF, the automated docketing system used to maintain the civil and criminal dockets of this District. If a minute order or other document is enclosed, please refer to it for additional information.

For scheduled events, motion practices, recent opinions and other information, visit our web site at [www.ilnd.uscourts.gov](http://www.ilnd.uscourts.gov).

# **EXHIBIT K**

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

<b>SOUTHERN ILLINOIS LABORERS' AND</b>	:	
<b>EMPLOYERS HEALTH AND WELFARE</b>	:	<b>CIVIL ACTION No. 06-CV-1818</b>
<b>FUND; NECA-IBEW WELFARE TRUST</b>	:	
<b>FUND; MIDWESTERN TEAMSTERS</b>	:	<b>JUDGE JOHN W. DARRAH</b>
<b>HEALTH AND WELFARE FUND; THE</b>	:	
<b>WELFARE FUND OF TEAMSTERS LOCAL</b>	:	<b>MAGISTRATE JUDGE</b>
<b>UNION 863; PLUMBERS &amp; PIPEFITTERS</b>	:	<b>GERALDINE SOAT BROWN</b>
<b>LOCAL UNION 630 WELFARE TRUST</b>	:	
<b>FUND; CLEVELAND BAKERS AND</b>	:	
<b>TEAMSTERS HEALTH AND WELFARE</b>	:	
<b>FUND; ELECTRICAL WORKERS BENEFIT</b>	:	
<b>TRUST FUND; FIRE &amp; POLICE RETIREE</b>	:	
<b>HEALTH CARE FUND, SAN ANTONIO,</b>	:	
<b>LABORERS' DISTRICT COUNCIL</b>	:	
<b>BUILDING AND CONSTRUCTION HEALTH</b>	:	
<b>AND WELFARE FUND; LABORERS'</b>	:	
<b>DISTRICT COUNCIL HEAVY AND</b>	:	
<b>HIGHWAY UTILITY HEALTH AND</b>	:	
<b>WELFARE FUND, NEW YORK CITY</b>	:	
<b>POLICE SERGEANTS BENEVOLENT</b>	:	
<b>ASSOCIATION HEALTH &amp; WELFARE</b>	:	
<b>FUNDS, individually, and</b>	:	
<b>On Behalf of All Others Similarly Situated,</b>	:	
<b>Plaintiffs,</b>	:	
<b>v.</b>	:	
<b>PFIZER INC.,</b>	:	
<b>Defendant.</b>	:	

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION  
TO MODIFY DISCOVERY**

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## INTRODUCTION

On September 3, 2007 this Court granted Plaintiffs' Motion for Leave to File a Second Amended Complaint (the "SAC"), and entered a briefing schedule for Pfizer's motion to dismiss the SAC. Plaintiffs filed the SAC the same day. As Plaintiffs' counsel described to the Court in the August 28, 2007 hearing, the SAC greatly streamlines the case by simplifying Plaintiffs' theory of damages. Put simply, the SAC alleges that Pfizer's false and misleading promotion of Lipitor resulted in Lipitor's price being higher than it would have been without such promotion. The Plaintiffs, third party payors ("TPPs") for Lipitor, paid too much for their participants' Lipitor. Damages, therefore, are the difference between the price the Plaintiffs paid for Lipitor and the price they would have paid had Lipitor's price not been wrongly inflated.

Plaintiffs intend to prove this theory by using commercially available data, Pfizer's own documents produced in discovery, third-party documents produced by Plaintiffs' subpoenae, and *Daubert*-compliant econometric analysis and statistical modeling. The Court's August 28, 2007 discovery Order ("the Order"), compelling the ten (10) remaining Plaintiffs to identify each off-label prescription for which they seek reimbursement, effectively compelled those Plaintiffs to obtain, analyze, and produce documents they did not have and would have to obtain from often unresponsive or uncooperative third parties. And to do this by September 26, 2007. Plaintiffs believed this obligation was unnecessary and unduly burdensome, even though Plaintiffs' damages theory under the First Amended Complaint was that they paid for too many off-label prescriptions.

Now, in the SAC, Plaintiffs expressly do **not** seek damages for the number of off-label prescriptions they claim resulted from illegal off-label marketing. Instead, the Plaintiffs seek damages for the dollar amount by which Lipitor's price was inflated by false and misleading overpromotion. The existing Order, therefore, not only compels the Plaintiffs to obtain, analyze and produce highly personal medical information the Plaintiffs do not have and must obtain from not necessarily amenable third parties, under a very short deadline, but to perform this extraordinarily burdensome work in service of a damages theory that Plaintiffs have affirmatively renounced and is not part of the SAC.

The administrative burdens and privacy invasions of this compelled discovery from the ten Funds now greatly outweigh any possible relevance that discovery might have. The Court should issue a superceding order relieving Plaintiffs from the now unnecessary burdens of obtaining, analyzing and producing thousands of medical records by September 26, 2007. The Court should also quash any outstanding subpoena issued by Pfizer seeking personal medical information for individual plan participants.

### **ARGUMENT**

#### **I. THE CURRENT DISCOVERY ORDER IS NO LONGER NECESSARY OR RELEVANT**

The current discovery Order requires Plaintiffs to obtain medical records release authorizations for each of their Lipitor-taking participants. For the ten Funds, this collectively involves over a thousand participants. This will require the Plaintiffs to engage in a communications effort explaining the need for this highly sensitive information. Inevitably, many participants will be slow in returning the forms, or will ignore them, or will have questions about the need for such highly sensitive personal health information.

Having answered the participants' questions, and, presumably, received at least a reasonable number of executed authorization forms, the Plaintiffs must then send those forms, with the Pfizer-approved cover letter, to the participants' Lipitor-prescribing doctors. But communicating with the doctors is neither automatic, nor simple nor administratively easy. First, a number of participants have more than one prescribing doctor. Second, for all these doctors, the Plaintiffs have to obtain addresses. The Plaintiffs and their PBMs do not typically keep such doctor-specific information.

Doctors often request payment before copying records, requiring further communications, correspondence, time and effort. The Plaintiffs would send funds in advance, but, not knowing the page volume of the particular participants' charts, what the particular doctor's per-page charge is, whether storage retrieval charges are involved, or numerous other variables, the Plaintiffs simply must request records and await a response. Busy doctors' offices do not often respond immediately.

And all of this time, effort and expense is so that Plaintiffs can produce information confirming their damages under their previous, now-abandoned, "number of off-label prescriptions" damages theory. On July 19, 2007, at a discovery hearing before Magistrate Judge Brown imposing these discovery obligations for the Florida Fund test case, the Court explained its ruling thus: "[W]hat we are going back to is the fact that there was an interrogatory posed by the defendants to identify the damages." July 19, 2007 Tr. at 13-14. The Court stated that the only information Plaintiffs must obtain is information that affects Plaintiffs' damage calculations: "And they have got . . . a lot of prescriptions for Lipitor, but not every prescription for Lipitor is going to fall within the damage calculation." *Id.* at 13. The Court specifically ruled that "the plaintiff shall

identify each Lipitor prescription written for an allegedly off label purpose that the Welfare Fund of Teamsters Local Union 863 *paid for on behalf of its participants.*” *Id.* at 16 (emphasis supplied).

The complaint under which Pfizer propounded its discovery is no longer operative. The SAC does not require detailed patient-specific medical information to determine Plaintiffs’ damages. The SAC does not allege that individual Plaintiffs were duped into paying for specific off-label prescriptions because of a fraudulent marketing campaign. Rather, the SAC alleges that Pfizer’s off-label or fraudulent marketing drove demand up and increased the price of Lipitor. *See, e.g.*, SAC at ¶ 30 (“Further, Pfizer expanded the market and demand for Lipitor, creating the artificially increased prices for Lipitor, not only by illegally promoting the off-label use of the drug, but also by concealing or minimizing the health risks associated with statin use, and by wrongfully promoting Lipitor as superior to and safer than other statin alternatives.”)

Plaintiffs’ damage calculations will not require time consuming collections and painstaking investigations of individual medical records and prescriptions. First, Plaintiffs will continue, through discovery, to gather additional information showing that Pfizer misrepresented Lipitor’s safety and efficacy in a uniform scheme of deceptive marketing that laid claim to superiority for Lipitor that did not exist or was, at best, marginal. Second, through commercially available data from Verispan and/or IMS Health that compiles information on patients taking Lipitor, such as their LDL levels and other risk factors of heart disease, Plaintiffs will show that Pfizer’s deceptive over-promoting marketing increased demand for Lipitor beyond what it would have been without the deception. Third, through expert economic testimony, Plaintiffs will show

that Pfizer inflated the price of Lipitor by artificially driving demand for Lipitor. Fourth, Plaintiffs will calculate damages, through expert testimony based, among other things, on Pfizer's own documents, publicly available prescription pricing, volume and market data, and *Daubert*-compliant econometric modeling, that determines the amount spent on Lipitor and subtracts the cost of Lipitor absent Pfizer's deceptive marketing.

Plaintiffs are not asking this Court to plow completely new ground or to invent new legal principles. Other respected courts have accepted this type of statistically-based and econometrically-modeled damages calculation in other medical and pharmaceutical litigation. *See, e.g., In re Neurontin Mktg. and Sale Practices Litig.*, No. 04-10981, 2007 WL 2437954 at \*20 (D. Mass. Aug. 29, 2007) (approving as a "widely-used statistical tool" a "time-series regression" analysis used by plaintiffs' expert to "calculate the total number of off-label prescriptions that were caused by defendants' off-label marketing activities"); *Klay v. Humana, Inc.*, 382 F.3d 1241, 1259-1260 (11<sup>th</sup> Cir. 2004) (certifying class of HMO subscribers in RICO action where damage calculations can be computed "according to some formula, statistical analysis, or other easy or essentially mechanical methods"); *In re Synthroid Mktg. Litig.*, 188 F.R.D. 295, 300 (N.D. Ill. 1999) (alleging suppression of information on the efficacy of generic substitutes artificially increased demand and price: "The question of liability, therefore, will turn on whether the defendants engaged in the alleged conduct, consisting primarily of the uniform suppression of material information, not on the individual decisions and circumstances of countless people along the chain of distribution of Synthroid."); *In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571, 578-579 (E.D.N.Y. 2007) ("defendant argues that plaintiffs' use of aggregate proof, rather than individualized proof, to establish reliance is

impermissible. This assertion is without merit. Statistical proof of reliance is appropriate in the RICO context where a ‘sophisticated, broad-based [scheme], by [its] very nature . . . likely to be designed to distort the entire body of public knowledge rather than to individually mislead millions of people[,]’ is alleged.”) (citations omitted).

## **II. REQUIRING PLAINTIFFS TO PRODUCE EVIDENCE OF INDIVIDUAL PRESCRIPTIONS IS UNDULY BURDENSOME**

The individual medical records Pfizer seeks contain the most intimate, private details of a patient’s physical and mental health. Plaintiffs have no intention of using these medical records to prove their case or to calculate damages. Pfizer will not need those documents in seeking to disprove Plaintiffs’ pricing claim. Nobody knows better than Pfizer how its marketing and promotional activities affect, or otherwise relate to, Lipitor’s market position and pricing.<sup>1</sup> Indeed, to a large extent, in pleading this theory, the Plaintiffs are necessarily playing on Pfizer’s home field.

Given the robust statistical data on which Plaintiffs will rely, the individual patient records have, at most, limited probative value in this case. In fact, Pfizer has not articulated how it plans to use this data to rebut the statistical evidence showing that illegal marketing inflated the price of Lipitor.

Rule 26(c) states that a court “may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden

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<sup>1</sup> To date, Pfizer has not informed Plaintiffs, after some fifteen months of discovery asking for it, whether Pfizer has located any Verispan data that Pfizer purchased reflecting information about Lipitor sales. Pfizer does, apparently, possess such Lipitor data purchased from IMS Health. But, despite June 2006 discovery requests clearly requesting such information, Pfizer has not yet advised whether it will produce such data. See Letters of Stephen G. Grygiel to Mark S. Cheffo, dated August 31, 2007 and September 6, 2007, Attachments A and B hereto, respectively. Plaintiffs have incurred costs of some \$17,000 to buy data from IMS Health that Plaintiffs are confident exists in some equivalent form in Pfizer’s own files. Plaintiffs’ subpoena to IMS Health will tell the tale. Plaintiffs expect to discuss these issues with Pfizer’s counsel, in a cooperative fashion, in the near future.

or expense.” In *American Intern. Specialty Lines Ins. Co. v. NWI-I, Inc.*, 240 F.R.D.

401, 412 (N.D. Ill. 2007), the court held:

[A] court may limit discovery if it determines that the burden of the discovery outweighs its likely benefit. To make such a determination, the courts consider what has been dubbed the proportionality test of Rule 26(b)(2)(iii): the needs of the case, the amount in controversy, the resources of the parties, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues.

Further, “to consider the nature of the hardship and its magnitude, [courts give] more weight to interests that have a distinctively social value than to purely private interests.” *Beauchem v. Rockford Products Corp.* No. 01 C 50134, 2002 WL 1870050, at \*2 (N.D. Ill. Aug. 13, 2002). Here, the value of individual patient data is small in comparison to the extremely intrusive nature of the discovery sought - private medical data of non-parties who happen to be members of a Fund that is alleging a damages theory that does not even implicate those records. Weighing the minimal to non-existent probative value of this highly sensitive personal medical information against the enormous administrative burdens of getting it, and the important privacy rights of the beneficiaries, this court should order that the discovery not be had.

#### **A. Beneficiary Data Has Limited Value In This Litigation**

Plaintiffs have no intention of using the medical records of its beneficiaries to prove or calculate damages. Such records are also irrelevant to rebut the statistical data cited by Plaintiffs. The number of Plaintiffs’ beneficiaries is tiny in relation to the nationwide numbers of anonymous patient records on which the statistical data Plaintiffs will use is based. The individual medical records of Plaintiffs’ beneficiaries would be of no value in challenging Plaintiffs’ statistical analysis.

**B. Producing Patient Data Would Be Unduly Burdensome Because It Impinges On The Privacy Of Plaintiffs' Beneficiaries.**

Producing the names and the private medical records of Plaintiffs' beneficiaries is also unduly burdensome because it unnecessarily violates the privacy of third parties, who have not brought this litigation. In *Neurontin* the plaintiffs similarly agreed to prove damages solely by statistical methods. The *Neurontin* court held that it would be unduly burdensome to produce patients' medical records:

After hearing, I conclude that the burden, expense and invasion of privacy of the proposed discovery outweighs its likely benefit. See Fed. R. Civ. P. 26 (b)(2) . . . If either party intends to call a treating physician to give an opinion on effectiveness, sanitized patient records shall be produced to the extent the physician is relying on his experience with treating that patient (as opposed to a clinical trial).

See Order, *In Re Neurontin Marketing, Sales Practices*, No. 1:04-cv-10981-PBS (D. Mass. filed September 27, 2006).

Similarly, the court in *Riley v. Walgreen Co.* 233 F.R.D. 496, 501 (S.D. Tex. 2005), held that a pharmacy did not have to turn over names and prescription information of its customers in litigation brought by plaintiff alleging that his prescription was improperly filled. Plaintiff requested the name and prescription data of other patients to determine if the pharmacy made other prescription-filling errors. *Id.* The court refused to require the production of such information: "Patient prescription drug orders and medication records contain highly sensitive and personal information . . . Given the extremely sensitive information at issue, the court agrees that both redaction of names and a confidentiality agreement are appropriate." *Id.* Here, just as in *Riley*, the privacy concerns of beneficiaries far outweigh the importance of their medical records to this litigation.

Furthermore, Plaintiffs do not keep medical records of beneficiaries in the regular course of business, and the process of obtaining medical records from doctors is unduly burdensome. *See Cohn v. Taco Bell Corp.*, No. 92 C 5852, 1993 WL 451463, at \*4 (N.D. Ill. Nov. 1, 1993) (holding plaintiff did not have to produce documents where the burden of gathering “records [was] quite large, in relation to the small value that they have in th[e] litigation”), *aff’d* 1994 WL 383975 (N.D. Ill. Jul 20, 1994). To point out just a few of the difficulties, gleaned from the experience of the test case protocol of the Plaintiff Plumbers & Pipefitters Local Union 630 Welfare Trust (“Florida Fund”), is highly instructive. The Florida Fund faced an enormous burden in complying with this Court’s June 16, 2007 Order to produce the medical records of its beneficiaries. First, Plaintiffs had to locate the doctors’ addresses by web-based searches and other investigations. Second, in a number of cases, Plaintiff was unable to locate which doctor had medical records of beneficiaries. Third, many doctors who had beneficiary medical records refused to turn them over without patient consent, citing HIPAA concerns and state laws protecting patient privacy. Obtaining these medical records would likely require additional litigation. Fourth, negotiating consent with each and every beneficiary to get their medical records will surely be very time-consuming and difficult and would also likely require additional litigation if fund participants do not want their private medical records in the hands of Pfizer.<sup>2</sup>

---

<sup>2</sup> For all these reasons, Plaintiffs also respectfully request that the Court quash all outstanding subpoenae issued by Pfizer for individual plan participants. The Federal Rules of Civil Procedure provide that a court shall quash or modify a subpoena if it requires disclosure of privileged information or subjects a person to undue burden. *See Fed.R.Civ.P. 45(c)(3)(A)*. Motions to quash are within the sound discretion of the district court. *Wollenburg v. Comtech Mfg. Co.*, 201 F.3d 973, 977 (7th Cir.2000) (citing *U.S. v. Ashman*, 979 F.2d 469, 495 (7th Cir.1992)).

## CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court enter an Order modifying its discovery order, quashing any outstanding Pfizer subpoena that seeks medical information from individual plan participants, and granting such other relief as the Court deems just and necessary.

DATED: September 6, 2007

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, George S. Bellas, certify that on this 6<sup>th</sup> day of September, 2007, a true and correct copy of Plaintiffs' Memorandum of Law in Support of Plaintiffs' Motion to Modify Discovery was filed electronically and served by electronic mail, facsimile and first-class mail upon the following counsel of record:

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# **EXHIBIT L**

UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

SOUTHERN ILLINOIS LABORERS' AND )  
EMPLOYERS HEALTH AND WELFARE )  
FUND; NECA-IBEW WELFARE TRUST )  
FUND; MIDWESTERN TEAMSTERS )  
HEALTH AND WELFARE FUND; THE )  
WELFARE FUND OF TEAMSTERS )  
LOCAL UNION 863; PLUMBERS & )  
PIPEFITTERS LOCAL UNION 630 )  
WELFARE TRUST FUND; CLEVELAND )  
BAKERS AND TEAMSTERS HEALTH )  
AND WELFARE FUND; ELECTRICAL )  
WORKERS BENEFIT TRUST FUND; FIRE )  
& POLICE RETIREE HEALTH CARE )  
FUND, SAN ANTONIO, LABORERS' )  
DISTRICT COUNSEL BUILDING AND )  
CONSTRUCTION HEALTH AND )  
WELFARE FUND; LABORERS' DISTRICT )  
COUNCIL HEAVY AND HIGHWAY )  
UTILITY HEALTH AND WELFARE )  
FUND, and NEW YORK CITY POLICE )  
SERGEANTS BENEVOLENT )  
ASSOCIATION HEALTH & WELFARE )  
FUNDS, individually, and on behalf of all )  
others similarly situated, )  
)   
Plaintiffs, )  
)   
v. )  
)   
PFIZER INC., )  
)   
Defendant. )  
)   
)

NO. 06-CV-1818

JUDGE JOHN W. DARRAH

MAGISTRATE JUDGE  
GERALDINE SOAT BROWN

**PFIZER'S OPPOSITION TO  
PLAINTIFFS' MOTION TO MODIFY DISCOVERY**

# **TABLE OF CONTENTS**

	Page
PRELIMINARY STATEMENT .....	1
ARGUMENT .....	2
I. ALLEGATIONS OF LIABILITY AND DAMAGES IN THE SAC PREMISED ON PFIZER’S PURPORTEDLY IMPROPER OFF-LABEL MARKETING OF LIPITOR FULLY SUBSTANTIATE THE CONTINUING VALIDITY OF THE COURT’S DISCOVERY ORDER OF AUGUST 28, 2007 .....	2
II. PLAINTIFFS HAVE NOT ESTABLISHED THAT RECONSIDERATION OR MODIFICATION OF THIS COURT’S ORDER IS WARRANTED .....	7
A. Plaintiffs’ Motion Seeks Reconsideration and Withdrawal (not “Modification”) of the Court’s Order .....	7
B. Reconsideration or Modification Is Unwarranted.....	9
C. The Arguments that Plaintiffs Make in Favor of Reconsideration or Modification Directly Contradict Plaintiffs’ Assertions to Judge Darrah that the SAC Would Not Moot Prior Discovery or This Court’s Discovery Orders.....	12
D. The Probative Value of the Discovery Sought by Pfizer, and Ordered by This Court, Is Underscored by the Fact that Plaintiffs’ Discovery Requests Seek the Same Information .....	13
III. PLAINTIFFS’ MOTION TO QUASH IS IMPROPER AND SHOULD BE DENIED.....	14
CONCLUSION .....	15

Defendant Pfizer Inc (“Pfizer”) respectfully submits this memorandum in opposition to Plaintiffs’ motion to modify this Court’s discovery Order of August 28, 2007 (the “Order”).

### **PRELIMINARY STATEMENT**

Contrary to Plaintiffs’ representations, the Second Amended Complaint (“SAC”) still contains the very same claims and allegations that led this Court to grant the discovery order that Plaintiffs now seek to vitiate. The SAC, like the Amended Complaint, continues to allege that Plaintiffs paid for improper off-label Lipitor prescriptions and that Pfizer promoted Lipitor for off-label purposes. In fact, while the SAC adds some new claims, and erases the term “off label” in a few spots, it continues to allege in no uncertain terms that Pfizer’s improper off-label marketing of Lipitor for the Funds’ “moderate risk” participants remains the primary predicate of Plaintiffs’ *liability* and damages theories. Plaintiffs may have re-cast their theory of how they believe damages can be calculated in this case, but their core allegations of liability, including their continued recitals in the SAC about alleged off-label promotion of Lipitor, still must guide the Court in defining the proper scope of permissible discovery. Pfizer’s interrogatory asking Plaintiffs to identify the off-label Lipitor prescriptions that they paid for remains highly relevant because Plaintiffs allege that Pfizer’s marketing caused prescribers to write improper off-label prescriptions, that those prescriptions were paid for by Plaintiffs, and ultimately led to an increase in the price of Lipitor. Just as before, Pfizer is entitled to know which off-label Lipitor prescriptions Plaintiffs’ participants filled, if any. Plaintiffs certainly know exactly how to obtain that information, and have had over a year to do it.

Moreover, in their zeal to thwart Pfizer’s year-old discovery request and this Court’s discovery orders, and argue yet again about intending to bypass discovery from their Funds in favor of using some kind of statistical damages model, Plaintiffs have invented a new procedural

device not tethered to the Federal Rules or the case law – a so-called “motion to modify discovery” – because they cannot satisfy this Circuit’s clearly defined criteria for a motion for reconsideration.<sup>1</sup> And of course it will not escape the Court’s notice that nowhere in Plaintiffs’ motion is any kind of “modification” actually sought. Rather, Plaintiffs seek to be relieved entirely of the discovery obligation imposed by the Court’s Order. Although this Court has twice rejected Plaintiffs’ efforts to prevent Pfizer from conducting discovery about Plaintiffs’ numerous allegations that they paid for specific types of off-label Lipitor prescriptions, and has explained to Plaintiffs on numerous occasions that Pfizer is not obligated to accept Plaintiffs’ proposed method of calculating damages, or tailor its discovery to fit neatly within Plaintiffs’ damages theory, Plaintiffs are back for a third bite of the apple. In light of Plaintiffs’ blistering allegations about Pfizer’s purported off-label marketing in their eighty-five page SAC, and their claims for over \$30 billion, the Order compelling a response to Pfizer’s interrogatory regarding off-label prescriptions ought not be “modified” in any way, much less vacated in its entirety, as Plaintiffs request.

### **ARGUMENT**

#### **I. ALLEGATIONS OF LIABILITY AND DAMAGES IN THE SAC PREMISED ON PFIZER’S PURPORTEDLY IMPROPER OFF-LABEL MARKETING OF LIPITOR FULLY SUBSTANTIATE THE CONTINUING VALIDITY OF THE COURT’S DISCOVERY ORDER OF AUGUST 28, 2007**

Even a cursory review of the Second Amended Complaint reveals that Plaintiffs’ characterization of it in their Motion to Modify bears little resemblance to the actual pleading. Indeed, it is difficult to understand how Plaintiffs can represent that the SAC renders this Court’s Order “no longer necessary or relevant.” Pls.’ Mem. at 3. Plaintiffs assert in their Motion that

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<sup>1</sup> Plaintiffs’ failure to file a procedurally proper, and cognizable, motion is, by itself, a sufficient basis to deny Plaintiffs’ motion.

“[t]he SAC does not allege that individual Plaintiffs were duped into paying for specific off-label prescriptions because of a fraudulent marketing campaign.” *Id.* at 5. Yet in the SAC, as in their two previous complaints, Plaintiffs continue to allege that because of Pfizer’s fraudulent marketing scheme they have paid for improper off-label Lipitor prescriptions:

- “As a result of Pfizer’s illegal, false and misleading marketing and promotion of Lipitor, Plaintiffs paid improperly inflated prices for Lipitor **and for an increased number of Lipitor prescriptions generated through Pfizer’s illegal marketing tactics.**” SAC ¶ 5 (emphasis added); *id.* ¶¶ 8-18 (alleging that each Plaintiff “paid wrongly inflated prices for Lipitor and for an increased number of Lipitor prescriptions generated through Pfizer’s illegal marketing campaign”); *see also, e.g., id.* ¶¶ 220, 227, 241, 260, 270, 274, 283, 290, 295, 301, 305.
- “A primary component of Pfizer’s illegal scheme has been its efforts to expand the market for Lipitor by promoting the off-label use of the drug” (*id.* ¶ 3), and this alleged “**off-label marketing . . . resulted in an artificially increased number of Lipitor prescriptions for which the Plaintiff Funds were required to pay . . .**” *Id.* ¶ 4 (emphasis added).
- “**Not knowing that Pfizer was engaged in a massive fraudulent scheme to cause the over-prescription of Lipitor, Plaintiffs did not take the necessary steps to ensure the drug was not being over-prescribed.**” *Id.* ¶ 70 (emphasis added).
- “Pfizer’s marketing of Lipitor for off-label uses also illegally caused Medicare, Medicaid, and other governmental programs to pay for off-label uses of Lipitor in violation of applicable payment guidelines.” *Id.* ¶ 73; *see also id.* ¶ 80.

Plaintiffs similarly spend page after page defining “off-label Lipitor prescriptions” in precisely the same way that they have since they filed their initial pleading over 17 months ago:

- “The ATP III guidelines, which are incorporated into Lipitor’s Label, have been adopted by third-party payors as the applicable criteria under which they will pay for Lipitor.” *Id.* ¶ 41.
- “[F]or a patient with multiple risk factors and a 10-year CHD risk of less than 10%, drug therapy can be considered *only* if the patient’s LDL is greater than or equal to 160 mg/dL, well above their goal of 130 mg/dL. . . . According to NCEP, there are 14.6 million people in this group who do not need drug therapy (those with multiple CHD risk factors and LDL levels between 130 mg/dL and 159 mg/dL). **This group is the primary target of Pfizer’s scheme.**” *Id.* ¶ 49 (bolded emphasis added).
- “Since the ATP III guidelines form the basis for Lipitor’s prescribing information, promoting Lipitor for patients who do not fall into the ATP III guidelines for drug therapy is illegal, off-label marketing.” *Id.* ¶ 67.

These and other allegations throughout the SAC (*see, e.g., id.* ¶¶ 108-77) confirm that Plaintiffs are asserting both that they paid more for Lipitor prescriptions, and that they paid for improper off-label prescriptions.<sup>2</sup> Accordingly, the same factual and legal rationale behind this Court's two prior orders directing Plaintiffs to respond to Pfizer's June 2006 interrogatory and identify the allegedly improper off-label Lipitor prescriptions for which they claim to have paid applies with equal force under the SAC.

Moreover, notwithstanding their numerous allegations that they have paid for improper off-label Lipitor prescriptions, to the extent that Plaintiffs seek to evade the Court's Order by claiming it is not relevant under their "price inflation" theory of causation and damages, Plaintiffs err in at least two fundamental respects. First, it is abundantly clear in the SAC that Plaintiffs' allegations regarding off-label marketing and improper prescriptions are not limited to their damages theory. To the contrary, these allegations lie at the heart of Plaintiffs' theories of liability as well. As such, evidence relating to off-label prescriptions that Plaintiffs allegedly paid for is certainly and properly discoverable.

Second, Pfizer submits (as this Court has repeatedly recognized) that Pfizer is not required to adopt Plaintiffs' theory of damages. *See, e.g.,* 6/13/07 Tr. [D.E. 95] at 32, 36-37. Moreover, Plaintiffs' securities-based, fraud-on-the-market or price inflation theory of causation has been expressly rejected by numerous federal and state courts outside the securities fraud context, and will likely be similarly rejected by Judge Darrah. It should not, therefore, be used to establish boundaries limiting Pfizer's discovery. Indeed, these courts have held that cases

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<sup>2</sup> Indeed, in their brief in support of their motion for leave to amend [D.E. 113], Plaintiffs asserted: "Plaintiffs, third-party payors who paid for an increased number of prescriptions for Lipitor resulting from Pfizer's illegal marketing practices, seek to establish that Pfizer has illegally expanded the market for Lipitor by deliberately engaging in deceptive marketing, including off-label marketing – promoting the drug for uses not identified on its FDA-approved label." Pls.' Mem. at 2.

involving prescription drug marketing are particularly ill-suited for the kind of market or statistical theories Plaintiffs seek to apply here. *See, e.g., Prohios v. Pfizer, Inc.*, 485 F. Supp. 2d 1329, 1337 (S.D. Fla. 2007) (rejecting “plaintiffs’ claim that they have been injured by ‘price inflation’ [as a result of Pfizer’s marketing of Lipitor] because, in the context of the pharmaceutical market, such damages are purely speculative”); *Heindel v. Pfizer Inc.*, 381 F. Supp. 2d 364, 369, 379-80 (D.N.J. 2004) (dismissing claims that “Defendants’ ‘uniform failure to disclose known cardiovascular risks associated with Celebrex and Vioxx caused consumers to pay artificially inflated prices for them’”); *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 172, 177-78 (D.D.C. 2003) (granting motion to dismiss action alleging that defendants’ “over-promotion of OxyContin inflated the price of the drug so that all class members ‘paid a higher price for OxyContin than if Defendants had not engaged in falsely advertising [the drug]’ because plaintiffs did not have Article III standing to sue based on a “fraud-on-the-market” theory of injury); *Int’l Union of Operating Eng’rs Local No. 68 Welfare Fund v. Merck & Co.*, No. A-22, 2007 N.J. LEXIS 1055, at \*38 (N.J. Sept. 6, 2007) (“[T]o the extent that plaintiff seeks to prove only that the price charged for Vioxx was higher than it should have been as a result of defendant’s fraudulent marketing campaign, and seeks thereby to be relieved of the usual requirements that plaintiff prove an ascertainable loss, the theory must fail.”);<sup>3</sup> *New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 178-79 (N.J. Super. Ct. App. Div. 2003) (affirming dismissal of action alleging that defendant’s marketing drove prices for its allergy medicine Claritin “up to artificially high levels,” finding that if fraud-on-the-market or price

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<sup>3</sup> Notably, this decision by New Jersey’s highest court unanimously reversed the certification of a class of third-party payors that sought to recover for alleged overpayments for Merck’s prescription pain reliever, Vioxx, 2007 N.J. LEXIS 1055, at \*10-11. The court expressly invalidated the appellate court’s endorsement of a price inflation theory, on which Plaintiffs relied in support of their motion to amend. *See* Pls.’ Reply [D.E. 123] at 10.

inflation theories were permitted, “the relationship between the alleged misstatement and the ascertainable loss suffered would become so attenuated that it would effectively disappear”).

As the *Heindel* court explained in dismissing plaintiffs’ “price inflation” or “fraud-on-the-market” theory of injury:

**In this context . . . such a theory is patently absurd.** It depends on the totally implausible predicate that, had some adverse information about side effects derived from [certain clinical] studies been more widely disseminated, the Plaintiffs would have paid *less* for Celebrex and Vioxx. However, (at the risk of stating the obvious) there is no prescription drug “market,” at least as that term is understood in the securities context. There, a “perfect market” or “efficient market” is assumed, and adverse information is expected to be quickly absorbed by the market, thus causing the price of the stock or commodity at issue to fluctuate.

381 F. Supp. 2d at 380 (bolded emphasis added). The *Prohios* court similarly held:

[T]o show any damages under the “price inflation” theory (assuming the price did incorporate information about Lipitor’s benefits), would require evidence of the *hypothetical* price at which Lipitor would sell if not for the allegedly misleading advertisements. **Determination of such hypothetical price, even with expert proof, is too speculative to be the premise of an “actual injury” under Article III.**

485 F. Supp. 2d at 1337 (bolded emphasis added).

Given this long line of well-reasoned authority squarely rejecting price inflation damages theories just like the one Plaintiffs have asserted in this action,<sup>4</sup> Pfizer should be permitted to

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<sup>4</sup> The cases on which Plaintiffs rely do not refute this wealth of authority. For example, in *In re Neurontin*, Judge Saris *denied* plaintiffs’ motion to certify classes of consumers and third-party payors seeking damages for purchases of Neurontin for off-label purposes. *In re Neurontin Mktg. and Sale Practices Litig.*, No. 04-10981, 2007 WL 2437954, at \*26 (D. Mass. Aug. 29, 2007). Although the denial was without prejudice, the court identified a number of problems with plaintiffs’ proposed aggregate statistical approach, including “the inability to identify which prescribing physicians were exposed to defendants’ fraudulent statements,” which the court noted “may be fatal to [plaintiffs’] theory of liability because physicians’ prescribing decisions could not have been caused by statements they never heard.” *Id.* at \*22; *see also id.* at \*24 (“there is no way,” under plaintiffs’ statistical model, “of identifying which doctors prescribed Neurontin based on this promotion as opposed to lawful off-label prescribing by a doctor who is exercising his own medical judgment”); *id.* at \*26 (“Here . . . to establish causation and injury the plaintiffs would need to conduct inquiries into the prescribing decisions of each class member’s physician.”); *id.* (finding a statistical approach “problematic” with respect to the third-party payor claims since it was not clear that they would be able “to distinguish between payments for on- and off-label

pursue discovery based on the liability and damages allegations of the SAC, and should not be limited by Plaintiffs' widely rejected and "patently absurd" price inflation damages theory.<sup>5</sup>

**II. PLAINTIFFS HAVE NOT ESTABLISHED THAT RECONSIDERATION OR MODIFICATION OF THIS COURT'S ORDER IS WARRANTED**

**A. Plaintiffs' Motion Seeks Reconsideration and Withdrawal (not "Modification") of the Court's Order**

Plaintiffs' so-called motion to modify discovery is, in fact, a motion to reconsider and vacate this Court's Order of August 28, 2007.<sup>6</sup> Motions to reconsider are not expressly provided for in the Federal Rules of Civil Procedure (*see Zepter v. Dragisic*, 237 F.R.D. 185, 187 (N.D. Ill. 2006)), and are generally entertained only "where: [1] the court has misunderstood a party; [2] the court has made a decision outside the adversarial issues presented to the court by the parties; [3] the court has made an error of apprehension (not of reasoning); [4] a significant change in the

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prescriptions"). Indeed, Judge Saris's observations both support the numerous federal and state court decisions cited above that have found a fraud-on-the-market or price inflation approach impermissible in cases like this one and highlight the problems with Judge Weinstein's decision in *In re Zyprexa* (on which Plaintiffs also rely) to permit plaintiffs to attempt to use aggregate, rather than individualized, proof to establish causation and injury. Moreover, in denying the parties' summary judgment motions, Judge Weinstein ruled only that plaintiffs may *try* to employ a theory of aggregate proof. The court emphasized that it was "not clear that plaintiffs can prove any damages, whether they attempt to prove overpayment on a case-by-case basis . . . or through statistical analysis." *In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571, 576 (E.D.N.Y. 2007). Of course, Judge Weinstein did not preclude defendant, as Plaintiffs seek to do here, from conducting discovery to establish that plaintiffs cannot prove damages through *either* a statistical method *or* "on a case-by-case basis" – the latter being the *only* permissible approach according to nearly every other court that has considered the issue in analogous cases.

<sup>5</sup> Of course, the Court need not determine whether Plaintiffs will ultimately prevail on their price inflation theory to resolve Plaintiffs' current motion. Even if there were merit to Plaintiffs' theory, the discovery sought by Pfizer that was the subject of the Court's Order would still be necessary to allow Pfizer to challenge some or all of Plaintiffs' theories of liability. Moreover, even under the price inflation damages theory, Pfizer is entitled to the discovery because it is directly relevant to a central element of that theory.

<sup>6</sup> Plaintiffs provide no authority for a "Motion to Modify Discovery."

law has occurred; or [5] significant new facts have been discovered.” *Wilson ex. rel. Adams v. Cahokia Sch. Dist. # 187*, 470 F. Supp. 2d 897, 913 (S.D. Ill. 2007).<sup>7</sup>

Motions to reconsider are generally not favored because they “needlessly take the court’s attention from current matters and visit inequity upon opponents who, prevailing in an earlier proceeding, must nevertheless defend their position again and again.” *Id.* (quoting *Berger v. Xerox Ret. Income Guar. Plan*, 231 F. Supp. 2d 804, 820 (S.D. Ill. 2002)). As the Seventh Circuit has explained: “It is not the purpose of allowing motions for reconsideration to enable a party to complete presenting his case after the court has ruled against him. Were such a procedure to be countenanced, some lawsuits really might never end, rather than just seeming endless.” *Frietsch v. Refco, Inc.*, 56 F.3d 825, 828 (7th Cir. 1995).

Here, the Court has not misunderstood a party, nor made an error of apprehension, and Plaintiffs do not rely on any new law or new facts in support of their motion. The allegations in the Amended Complaint that supported this Court’s prior Orders are repeated in the SAC. Plaintiffs have argued, on several occasions before this Court, that they should not be required to identify off-label prescriptions because they can establish damages using an unidentified statistical model. This Court has repeatedly rejected Plaintiffs’ arguments and held that Pfizer: (1) is entitled to discover whether Plaintiffs reimbursed for any off-label Lipitor prescriptions as Plaintiffs allege and otherwise conduct discovery to prepare its own defense; and (2) is not required to subscribe to Plaintiffs’ damages theory. Moreover, as this Court has further recognized, not all off-label prescriptions can give rise to liability. Because physicians may, in their considered medical judgment, lawfully write off-label prescriptions for their patients, only

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<sup>7</sup> Motions for reconsideration have been addressed in the context of discovery orders. See *SmithKline Beecham Corp. v. Apotex Corp.*, 194 F.R.D. 624, 625-27 (N.D. Ill. 2000) (denying plaintiffs’ motion for reconsideration of the court’s order granting defendant’s motion to compel in part); *Zepter*, 237 F.R.D. 188-90 (denying plaintiff’s motion for reconsideration of the court’s order as to privilege issues).

*improper* off-label prescriptions (i.e., prescriptions written because of Pfizer's allegedly unlawful marketing activities) may figure in the liability calculus. *See* 6/13/07 Tr. [D.E. 95] at 35, 38.

A motion for reconsideration is "not an opportunity for a disappointed party to rehash the same arguments that it raised earlier." *Zepter*, 237 F.R.D. at 187. No matter how it is styled, the fact is that Plaintiffs have not provided any legitimate basis for their motion.

**B. Reconsideration or Modification Is Unwarranted**

Plaintiffs argue that having to actually identify the off-label prescriptions of their beneficiaries is unduly burdensome, that the data is of "minimal to non-existent probative value," and that producing it "impinges on the privacy of Plaintiffs' beneficiaries." Pls.' Mem. at 8, 9. Neither of these objections is credible.

Their hollow protests aside, there is no question but that Plaintiffs can comply with the Court's Order. Both in open court, and in interrogatory responses, Plaintiffs have laid out the steps they will need to take to respond to Pfizer's interrogatory. That a response may require time and considerable effort is a function of the vast breadth and scope of Plaintiffs' complaint, not of any action or wrongdoing on the part of Pfizer. Had Plaintiffs diligently investigated the basis of their claims and collected relevant evidence in support of those claims *before* filing suit, they would now be well on their way to producing the discovery to which Pfizer is plainly entitled. Having dragged their feet for months, Plaintiffs ought not be heard to complain about – much less be relieved of – a burden entirely of their own making.

Notably, *after* Plaintiffs' motion to amend the complaint had been granted, Plaintiff Plumbers and Pipefitters served discovery responses that clearly contradict the arguments in their present motion and demonstrate that even under Plaintiffs' fanciful notion of proving entitlement

to \$30 billion in damages by reliance on some kind of statistical model,<sup>8</sup> they will need to – and indeed are expected to – identify the off-label prescriptions for which they claim to have paid.

Specifically, in a Request for Admission, Pfizer asked Plumbers and Pipefitters (“Plumbers”) to

admit that a Lipitor prescription for one of your participants was not written for an improper off-label purpose, as that term is defined in the Amended Complaint, if the participant’s prescribing physician wrote the prescription based solely on his or her medical judgment and assessment of the participant’s health status.

*See* Plumbers and Pipefitters Response to Pfizer’s Second Request for Admission, No. 13,

(attached hereto as Ex. A) (emphasis added). Although Plumbers refused to admit, contrary to its counsel’s prior concessions (including before this Court), that a Lipitor prescription would not be improper if a physician wrote it based solely on his or her medical judgment (*see* 6/13/07 Tr. 27), the Fund went on, in its response, to spell out the details about how it intended to search for and identify off-label prescriptions and determine the number of prescriptions filled by its participants for improper off-label purposes:

**Denied.** Answering further, Plaintiff states that Lipitor’s on-label indications are set forth on Lipitor’s label. Any uses that are not expressly authorized by Lipitor’s label are considered off-label uses. **In order to determine the total number of participants that received Lipitor for off-label uses, Plaintiff will seek to identify its Lipitor taking Fund participants, seek to obtain their medical records for the relevant time period, have those records reviewed by a consulting dyslipidemia/hypercholesterolemia expert, and in cases where Plaintiff’s experts determine that the information reviewed indicates that a participant’s prescription for Lipitor did not match Lipitor’s on-label indications, Plaintiff will identify such participants as receiving Lipitor for off-label uses.** After identifying participants that received Lipitor for off-label uses, and assuming Plaintiff is unable to obtain medical records for all Lipitor

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<sup>8</sup> Notwithstanding Plaintiffs’ repeated references to a statistical model for a purported nationwide class of third-party payors, Plaintiffs have not moved for class certification, much less had a class certified. Accordingly, what is before this Court are claims by eleven individual Plaintiffs, each of whom must independently prove its own claims and respond to Pfizer’s discovery. *See, e.g., Palmer v. City of Chicago*, 755 F.2d 560, 570 (7th Cir. 1985) (“[N]amed plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent.”) (quoting *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 40 n.20 (1976) (additional internal quotation marks and citation omitted)).

taking Fund participants, Plaintiff (through an expert) anticipates performing a statistical analysis in order to calculate the rate of Lipitor's off-label use within Plaintiff's participant population. **Thus, based on actual record review and statistical analysis Plaintiff will determine the number of prescriptions filled by its participants for improper off-label purposes.**

Ex. A, No. 13 (emphasis added). Because Plaintiffs' own proposed damages theory and methodology rests on the identification of specific off-label Lipitor prescriptions, there can be no legitimate claim of undue burden or prejudice resulting from the requirement that Plaintiffs disclose such information at this juncture.

Plaintiffs' claims about the privacy of their participants is another red herring. Plaintiffs have a contractual right to obtain such information concerning their participants,<sup>9</sup> and indeed, Plaintiff Plumbers has already obtained the information and provided it to Pfizer. In its three-page letter to doctors regarding the collection of its participants' medical records, the Fund assured doctors that they were "authorized to make this disclosure." 7/30/07 letter from Plumbers to physicians at 2 (attached as Ex. A to D.E. 106). The letter noted that: "our members have authorized us, in our plan documents, to obtain such . . . information when the Fund is making a claim based on benefits the Fund paid on behalf of its members;" "HIPAA permits disclosure of protected health information in a judicial proceeding"; and "all protected health information exchanged between parties in the case is subject to a HIPAA-authorized Confidentiality Agreement." *Id.*

The comprehensive protective order in place in this litigation was reviewed and commented on, before it was entered, both by Plaintiffs' counsel in this case, and several of the

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<sup>9</sup> Available documents confirm that the Funds' own written policies expressly allow them to disclose the requested information for a number of purposes, including to obtain reimbursement. *See, e.g.*, Southern Illinois Laborers' & Employers Health & Welfare Fund Summary Plan Description 2005 at 53-54 (attached as Ex. A to D.E. 101).

Funds' HIPAA experts, for the specific purpose of insuring that participant information would be protected.

**C. The Arguments that Plaintiffs Make in Favor of Reconsideration or Modification Directly Contradict Plaintiffs' Assertions to Judge Darrah that the SAC Would Not Moot Prior Discovery or This Court's Discovery Orders**

To obtain leave to file their SAC, and to counter Pfizer's showing that amending the complaint again at this late date would prejudice Pfizer because it had expended significant time and resources on discovery concerning the claims of the First Amended Complaint, Plaintiffs represented to Judge Darrah that they would comply with this Court's orders and that Pfizer would "surely suffer no undue prejudice" because Plaintiffs' discovery obligations would be unchanged. Pls.' Reply Mem. [D.E. 123] at 5.

For example, at the hearing before Judge Darrah on September 4, 2007, Plaintiffs argued that the SAC "overlap[s] and dovetail[s]" the prior complaint and that Pfizer would not be prejudiced because it would have a right to obtain and use the discovery and rulings already conducted over the past seventeen months. *See* 9/4/07 Tr. [D.E. 138] at 4-5. Indeed, although Plaintiffs asserted that they did not agree that doctor-by-doctor, participant-by-participant discovery would be necessary under the SAC, they ensured Judge Darrah in their reply memorandum that "Plaintiffs . . . have complied **and will continue to comply with all orders issued by the Court.**" Pls.' Reply Mem. at 3 (citation omitted) (emphasis added).

Having argued in support of their motion to amend that Pfizer would not be prejudiced by Plaintiffs' amendment because it would remain entitled to the same discovery it had requested and that this Court had ordered, Plaintiffs should not be permitted to now deny Pfizer access to that very discovery.

**D. The Probative Value of the Discovery Sought by Pfizer, and Ordered by This Court, Is Underscored by the Fact that Plaintiffs' Discovery Requests Seek the Same Information**

Notwithstanding Plaintiffs' claims that the identification of off-label Lipitor prescriptions is no longer necessary or relevant, Plaintiffs are aggressively seeking the same information from Pfizer and non-parties. For example, Plaintiffs just served a subpoena upon a non-party provider of prescription data and analysis, IMS Health, seeking:

All information provided to Pfizer, Inc. relating to Lipitor from 1997-present, including, without limitation, information relating to Lipitor prescriptions, indications for which Lipitor prescriptions were written, **and lipid profiles (HDL, LDL, triglycerides, risk factors, etc.) of patients receiving Lipitor prescriptions.**

IMS Health Subpoena (attached hereto as Ex. B) (emphasis added).

In addition, Plaintiffs are currently seeking from Pfizer patient-specific information about cholesterol levels and other risk factor information:

Particularly relevant to our case – and I know of course, you take a different view – is the PDDA Audit information including patient demographics. That demographic information “include[s] contact location, height, weight, age, gender, race, blood pressure, **cholesterol levels (total, HDL, LDL, triglycerides),** insurance type and body mass index.”

8/2/07 letter from S. Grygiel to M. Cheffo at 2 (attached hereto as Ex. C).<sup>10</sup> At great expense and effort, Pfizer is currently reviewing a vast collection of electronic data to identify such information. Apparently, Plaintiffs believe that the information covered by the “current discovery order is no longer necessary or relevant” (Pls.’ Mem. at 3), unless it is Pfizer or a non-party that has to search for and produce such information. Plaintiffs continue to make claims

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<sup>10</sup> Of course, as Plaintiffs and this Court have recognized, even if aggregate, population-based statistical data exists about the millions of patients who are prescribed Lipitor by their physicians, each Plaintiff must still establish that it sustained damages by reimbursing for specific improper off-label prescriptions for its own participants as a result of Pfizer’s alleged conduct. *See, e.g.*, 6/13/07 Tr. at 32-33, 36-37, 43.

that they paid for off-label Lipitor prescriptions as a result of Pfizer's conduct, and as such, should not be relieved of their current discovery obligations on this exact issue.

### **III. PLAINTIFFS' MOTION TO QUASH IS IMPROPER AND SHOULD BE DENIED**

Plaintiffs' request – in a footnote – that this Court quash “all outstanding subpoenae issued by Pfizer for individual plan participants” (Pls.' Mem. at 10 n.2), is procedurally improper and should be denied on multiple grounds. As a threshold matter, Rule 45(c)(3)(A) vests “the issuing court” with the sole authority to “quash or modify” a subpoena. Fed. R. Civ. P. 45(c)(3)(A). The subpoenas at issue were not issued out of this District. Accordingly, this Court is not the proper forum for Plaintiffs' motion. *See Kearney v. Jandernoa*, 172 F.R.D. 381, 383 n.4 (N.D. Ill. 1997) (“[A] motion to quash, under Rule 45(c)(3)(A), must be filed and decided in the court from which the subpoena issued.”); *Kruse Inc. v. United States*, No. 1:99-CV-428, 2000 WL 35516935, at \*2 (N.D. Ind. Sept. 29, 2000) (“[M]otions to quash are governed by Rule 45, which grants only the issuing court the power to quash or modify its subpoenas.”). Plaintiffs should certainly be familiar with this Rule as they have served over 40 non-party subpoenas to numerous individual scientists, including various members of the NCEP Guidelines Panel.

Moreover, Plaintiffs neither reference a motion to quash in their Notice of Motion nor provide any legal or factual support for such a motion within their memorandum. Nor have Plaintiffs met and conferred with Pfizer regarding any objections they have to Pfizer's third-party subpoenas, as required under LR 37.2. Plaintiffs' request is thus premature and improper.

Further, Plaintiffs lack standing to challenge the subpoenas at issue since they are directed to third parties. *See, e.g., Vogue Instrument Corp. v. Lem Instruments Corp.*, 41 F.R.D. 346, 348 (S.D.N.Y. 1967) (denying defendants' motion to quash subpoenas since “the defendants, being neither persons in possession or control of the documents, nor the persons to whom the subpoenas are directed, lack standing to attack the subpoenas”); *Kessel v. Cook*

*County*, No. 00 C 3980, 2002 WL 398506, at \*2 (N.D. Ill. Mar. 14, 2002) (noting that parties only have standing to quash subpoenas issued to third parties where the party claims a personal right or privilege in the documents sought). Plaintiffs do not and cannot claim a personal right or privilege in the documents Pfizer has requested.

**CONCLUSION**

For the foregoing reasons, Pfizer respectfully requests that the Court deny both Plaintiffs' motion to modify the Court's Order of August 28, 2007 and their request that the Court quash Pfizer's subpoenas.

DATED: September 19, 2007

Respectfully submitted,

**PFIZER INC**

By its attorneys,

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**CERTIFICATE OF SERVICE**

I, Andrew J. Jarzyna, an attorney, certify that on this 19th day of September, 2007, one true and correct copy of the foregoing Opposition to Plaintiffs' Motion to Modify Discovery was served through this Court's electronic filing system upon the following counsel for Plaintiffs: George S. Bellas, gsb@cliffordlaw.com; Robert A. Clifford, rac@cliffordlaw.com; Sidney S. Liebesman, sliebesman@gelaw.com; Patrick J. O'Hara, patrick@cavanagh-ohara.com; and Thomas K Prindable, tkp@cliffordlaw.com.

/s/Andrew J. Jarzyna  
Andrew J. Jarzyna

# **EXHIBIT M**

**UNITED STATES DISTRICT COURT  
FOR THE Northern District of Illinois – CM/ECF LIVE, Ver 3.0  
Eastern Division**

Southern Illinois Laborers' and Employers Health and  
Welfare Fund, et al.

Plaintiff,

v.

Case No.:  
1:06-cv-01818  
Honorable John W.  
Darrah

Pfizer Inc.

Defendant.

---

**NOTIFICATION OF DOCKET ENTRY**

This docket entry was made by the Clerk on Wednesday, September 26, 2007:

MINUTE entry before Judge Geraldine Soat Brown : Motion hearing held.  
Defendant's motion to compel [133] is taken under advisement. Plaintiffs' motion to  
modify discovery [136] is taken under advisement. The Court will issue a ruling by mail.  
Notice mailed by judge's staff (ntf, )

**ATTENTION:** This notice is being sent pursuant to Rule 77(d) of the Federal Rules of  
Civil Procedure or Rule 49(c) of the Federal Rules of Criminal Procedure. It was  
generated by CM/ECF, the automated docketing system used to maintain the civil and  
criminal dockets of this District. If a minute order or other document is enclosed, please  
refer to it for additional information.

For scheduled events, motion practices, recent opinions and other information, visit our  
web site at [www.ilnd.uscourts.gov](http://www.ilnd.uscourts.gov).

# **EXHIBIT N**

**TRANSCRIBED FROM DIGITAL RECORDING**

IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

SOUTHERN ILLINOIS LABORERS'S AND )  
EMPLOYERS HEALTH AND WELFARE FUND, )  
et al., )

Plaintiffs, )

vs. )

PFIZER, INC., )

Defendant. )

No. 06 C 1818

Chicago, Illinois

September 26, 2007

9:45 A.M.

TRANSCRIPT OF PROCEEDINGS - Motion  
BEFORE THE HONORABLE GERALDINE SOAT BROWN, Magistrate Judge

**APPEARANCES:**

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**NOTE: Please notify of correct speaker identification.  
DISTORTED RECORDING ON PODIUM MICROPHONE.**

1 (Proceedings held in open court:)

2 THE CLERK: 06 C 1818, Southern Illinois Laborers's  
3 Employers Health and Welfare Fund versus Pfizer.

4 THE COURT: Good morning.

5 MR. GRYGIEL: Good morning again, your Honor. Steve  
6 Grygiel for the plaintiffs.

7 MR. CHEFFO: Good morning, your Honor. Mark Cheffo,  
8 C-h-e-f-f-o, for Pfizer.

9 MR. JARZYNA: Andy Jarzyna, J-a-r-z-y-n-a, for Pfizer.

10 THE COURT: All right. Well, we're here on two  
11 motions, one from each side, the defendant's motion to compel  
12 and the plaintiffs's motion to modify discovery.

13 I did get a copy of the transcript of proceedings  
14 before Judge Darrah and have read that.

15 I have a preliminary note, which is I have received  
16 about an inch and a half stack of papers with a cover paper  
17 that says plaintiffs's reply in support of plaintiffs's motion  
18 to modify discovery. I note that the way this was delivered  
19 was the legal argument is stapled, and the rest of it, all the  
20 exhibits, are loose papers bound by a very skinny rubber band  
21 with no protruding tabs.

22 Local Rule 5.2 requires that the Judge's paper copy of  
23 any document must be securely bound on the left side with  
24 protruding tabs and a list of exhibits.

25 I am not going to accept this document. If it is not

1 submitted to me in the appropriate format, I'm not even going  
2 to try to do anything with it. Because even to open up this  
3 rubber band would probably result in a sheaf of papers being  
4 dumped on my floor.

5 I'm directing my courtroom deputy to give it back to  
6 the plaintiffs's counsel. And if you do not submit it in the  
7 appropriate format to me, I'm not even going to consider it.

8 And that goes for everybody. We just get too much  
9 paper in this court. And the possibility of that rubber band  
10 breaking and falling all over the floor, making a big mess in  
11 the office, and leaving your argument in literal shambles, is  
12 so real I'm not going to even start with it. So that is a  
13 prefatory note. That goes for everybody.

14 So we are here on the two motions, the motion to  
15 compel and the motion to modify.

16 Just bring me up to date as to where things are. But  
17 before I do, we have the motion in the Randolph case.

18 (Discussion off the record.)

19 THE COURT: Go ahead, Mr. Grygiel.

20 MR. GRYGIEL: Apologies for the filing, your Honor.  
21 We'll see that that be corrected.

22 Bringing you up to date, obviously we have got these  
23 two motions here.

24 In the way of bringing you up to date further,  
25 Mr. Cheffo has sent me, I believe, three letters in the last

1 week. I think there were two last Thursday, and maybe one last  
2 Friday. And they deal with other discovery matters where I  
3 believe he has found deficiencies in our responses.

4 I have made some points that I think are relevant to  
5 deficiencies in their production.

6 And we have agreed to correspond about that. I told  
7 Mark I would get back to him yesterday. I didn't.  
8 Unfortunately I had expert witness discovery in another case  
9 that took an awful lot longer than I thought it was going to  
10 take. And I didn't get there, but I will.

11 So I know we have at least three outstanding matters,  
12 some deficiencies in our alleged responses to request to admit,  
13 arguments that I have made concerning some of the -- what I  
14 consider to be defaults in production, and then we have some  
15 deposition issues to work out. I think those are the major  
16 categories. I might have left one or two out.

17 But there is more to come, I just haven't gotten to it  
18 yet, your Honor.

19 THE COURT: Mr. Cheffo.

20 MR. CHEFFO: I think that's fair, your Honor. I hope  
21 there is not more to come. We have generally been able to try  
22 and work out many of the issues, so hopefully we will do the  
23 same. And the day certainly is not a problem. We'll work it  
24 out this week.

25 And you know that there is a briefing schedule in

1 place for the motion to dismiss --

2 THE COURT: Uh-huh.

3 MR. CHEFFO: -- which will bring us, I believe,  
4 towards the end of November --

5 MR. GRYGIEL: Right.

6 MR. CHEFFO: -- before Judge Darrah. And currently we  
7 have a December 31st fact discovery cutoff. And we have a  
8 March 31st expert discovery cutoff. I think that's pretty much  
9 it.

10 The only -- probably at some point, to the extent that  
11 those dates remain in effect and no motions have been made to  
12 change them, with respect to experts, I think we would probably  
13 approach this Court or maybe even submit something  
14 joint -- jointly as far as how we would use the three months  
15 for experts, you know, to have reports and depositions and  
16 things of the like. And there is no date set.

17 THE COURT: I note that Judge Darrah did not stay  
18 discovery pending the briefing on the motion to dismiss, so I  
19 guess we run on two tracks here.

20 And the -- if the -- I guess I'm trying to figure out  
21 what the various scenarios are:

22 One, the motion to dismiss is denied and the second  
23 amended complaint becomes the operative pleading.

24 Two, if the motion to dismiss is granted, then what?  
25 Then what -- what is the status of the case? What -- if the

1 motion to dismiss the second amended complaint is granted, is  
2 there any -- is there anything -- is there any controversy in  
3 the court?

4 MR. GRYGIEL: Well, there would be, I suppose, your  
5 Honor, if the Judge dismisses the second amended complaint with  
6 prejudice or with leave to amend certain claims. That would  
7 probably have a lot to do with it I would think --

8 THE COURT: I mean --

9 MR. GRYGIEL: (Unintelligible).

10 THE COURT: -- what if he just says, I don't find this  
11 theory viable? What if he does that? What if he says it is  
12 not a viable theory?

13 MR. GRYGIEL: Well, in that case, your Honor, you're  
14 going to be relieved of the burden of Mr. Cheffo and I being,  
15 here. As much as we have been here lately, I think that's  
16 true.

17 MR. CHEFFO: Well, that -- we -- and I'm not here to  
18 certainly question Judge Darrah or reargue what -- you know,  
19 that's why you see sort of at the end of the hearing I -- we  
20 are in an odd situation, I think, as the Court has recognized.  
21 And sometimes things just happen in litigation. But there is a  
22 good chance that discovery will close, and perhaps even expert  
23 discovery will close in this case before we even have a ruling  
24 as to whether the plaintiffs have stated a cause of action,  
25 state a claim in the pleadings.

1           It is what it is, at least for the time being. Judge  
2 Darrah is the master of that decision.

3           THE COURT: That's right.

4           MR. CHEFFO: But that is what I tried to avoid,  
5 frankly, very early on in this case by aggressively asking the  
6 plaintiffs and Judge Darrah for a motion to stay discovery. It  
7 was opposed and denied. So we are now at a point where Pfizer  
8 is faced with, you know, a \$30 billion dollar claim and very  
9 significant discovery deficiencies outstanding. And frankly  
10 I -- you know, I and, I think, my client have no choice but to  
11 push ahead.

12           THE COURT: Well, let's take the first issue, which is  
13 a sort of -- the first issue of the defendant's motion to  
14 compel overlaps with the plaintiffs's motion to modify.  
15 Agreed?

16           MR. GRYGIEL: That's right, your Honor.

17           THE COURT: Okay. And the real question is whether to  
18 proceed on with the discovery of a per -- per prescription  
19 basis; that is, identifying the individual prescriptions  
20 claimed to be the improperly paid for prescriptions for the  
21 improper off-label Lipitor.

22           And the defendants have so far been successful in  
23 getting me to order that that be produced, first by one fund  
24 and then by the second fund. The plaintiff is objecting and  
25 saying that it is -- number one, it is too burdensome; number

1 two, it is mooted by the new complaint.

2 Right?

3 MR. GRYGIEL: That's correct, your Honor.

4 THE COURT: Well, it seems to me -- I don't know the  
5 answer to the question of whether it is mooted by the new  
6 complaint. I really want to study these with more care than I  
7 have been able to study them.

8 But one question I would pose to the plaintiffs is if  
9 it is indeed your position that the effort to identify  
10 individual prescriptions that were allegedly over -- written  
11 that caused the funds to go out of pocket improperly is too  
12 burdensome and too difficult and too invasive of privacy and  
13 all the other reasons you have just given, and not in your  
14 control, is it possible to reach a stipulation that could be  
15 read to the jury, if necessary, to the effect that the  
16 plaintiff stipulates that it is -- has not and is not  
17 attempting to identify individual prescriptions, and have  
18 something to that effect.

19 Now what the defendant doesn't want is it doesn't want  
20 a situation in which there is argument that we were out of  
21 pocket for all these prescriptions and then never have the  
22 ability to go behind that argument.

23 Am I right, Mr. Cheffo?

24 MR. CHEFFO: I think that's right. But I also  
25 just -- and I don't want to interrupt the Court on this. I

1 think that that's certainly a component.

2 But I think another component here is the plaintiffs  
3 have focused only on damages. And I think we have an issue  
4 here that -- and we have pointed to those 166 paragraphs that  
5 are exactly the same -- the real issue is here they say, I  
6 think, and Mr. Grygiel will correct me, one issue is we paid  
7 more for Lipitor. So that's the same complaint that's always  
8 been in the case.

9 THE COURT: Right.

10 MR. CHEFFO: The other is as a result of your  
11 off-label conduct you drove up demand and were able to charge a  
12 higher price.

13 And we then say we're going to produce this by some  
14 statistical model.

15 So certainly we have 11 funds. We have no motion for  
16 class certification on file at this point. We're entitled to  
17 basically say during discovery, well, one, you are seeking  
18 recovery in your complaint for the off-label prescriptions as  
19 prescriptions; and; two, you're saying that we have promoted  
20 off-label, and that drove up the cost.

21 So certainly during discovery we're entitled to  
22 explore whether they in fact paid for any off-label  
23 prescriptions or were written.

24 And, frankly, they cite two cases for this, the  
25 Zyprexa case and the Neurontin case. And if you read those

1 cases, not even that closely, what Judge Weinstein does is  
2 Zyprexa, it says, well, I may consider the off-label -- the  
3 price inflation theory, but he certainly doesn't preclude the  
4 defendants from conducting discovery on it. In fact he denies  
5 that plaintiffs's motion for summary judgment on that ground.

6 Similarly, in the Neurontin case discovery was  
7 conducted. Judge Saris says, well, you may have to call the  
8 individual doctors. To the extent there is patient issues,  
9 maybe we'll deal with those.

10 But that was -- the point is, you know, for today on  
11 discovery the issue is is this relevant. And they have moved  
12 off -- I wouldn't think they would make the argument that it is  
13 not relevant because you're going to hear in connection with  
14 some of the other issues they have asked Pfizer for the same  
15 information. In fact, they subpoenaed IMS and Verispan for the  
16 identical information.

17 Their only real argument is that it poses some  
18 burden. Well, you know, what we have been doing for the last  
19 17 months is incredibly burdensome. We have produced almost  
20 half a million pages of documents. We continue to produce it.

21 In fact the same kind of detailed information that  
22 they are asking for from IMS, I get almost daily letters from  
23 Mr. Grygiel saying where it is. And in fact we're looking for  
24 it.

25 And the final point I would just have the Court

1 understand is that what this IMS and Verispan, you have no --  
2 no reason to understand what it is and what it isn't. But  
3 basically I think the plaintiffs have created this perception  
4 that there is this data out there that says, you know, Mark  
5 Cheffo has an LDL level of XYZ, and he is a fund participant,  
6 and here is his two more risk factors.

7 That's not what this data is. This data might say,  
8 you know, population groups are 65. But it doesn't cross  
9 reference the kind of information. In other words, you  
10 couldn't look at the IMS, as far as I understand it, you  
11 couldn't look at this data and be able to determine whether an  
12 off-label prescription was written, much less whether it was  
13 written for an improper purpose.

14 So at the core, for all the reasons that the Court  
15 stated much more articulately than I can, why this is at this  
16 point relevant and why it should be discoverable still apply  
17 based upon this complaint.

18 THE COURT: First, before I hear from you,  
19 Mr. Grygiel, I do want to give you plenty of time to make these  
20 arguments because what I am thinking of doing is listening to  
21 you today, going back, reading these materials, and either  
22 having you come back for further argument if I need more  
23 clarification or, I think at this point, the better thing for  
24 me to do would be try to write up an opinion that then could  
25 be -- the focus, if need be, of some objections to Judge Darrah

1 and that may focus the issue more specifically and give Judge  
2 Darrah -- (unintelligible) the benefit of my thought of it, but  
3 at least a set -- a set piece of my thoughts so that it is a  
4 little clearer than I can do on -- adlibbing from the bench.

5 So -- but before I do that, I ask your indulgence to  
6 allow the Randolph case to come forward.

7 If you would call the Randolph case because this will  
8 be short.

9 (Whereupon the Court turned to other matters on her call:)

10 THE CLERK: 06 C 1818, Southern Illinois Laborers's  
11 Employers Health and Welfare Fund versus Pfizer.

12 THE COURT: Okay. Back.

13 Mr. Grygiel.

14 MR. GRYGIEL: I think it is my turn, Judge.

15 THE COURT: It is.

16 MR. GRYGIEL: Thank you.

17 Perhaps the first thing to point out is my tally of  
18 the number of times I just heard the words off-label come out  
19 of Mr. Cheffo's mouth. The transcript will tell us accurately  
20 what that number is. I think I counted eight.

21 The entire point of the second amended complaint was  
22 to change the nature of the damages theory of this case from an  
23 off-label case, which arguably would require the counting up,  
24 the actual identification of the number of off-label  
25 prescriptions for which damages were claimed. We found that

1 was too burdensome to do. And I was expressly clear in this  
2 court and in front of Judge Darrah when I said, let me be  
3 perfectly clear or words to that effect, that's why we're  
4 changing this. That's why we're altering the theory of  
5 damages.

6 In fact, your Honor, you asked me whether it were true  
7 that if our motion for leave to file a second amended complaint  
8 were granted would I be back before you with a motion arguing  
9 that this individualized discovery was now unnecessary. And I  
10 replied, yes, your Honor. I could not have been more clear.  
11 That is why we did it.

12 Now Mr. Cheffo says, well, wait a minute, they are  
13 still asking for damages for off-label prescriptions. And the  
14 answer is, which will be probably best answered, your Honor, by  
15 your close review of the second amended complaint, is, no, we  
16 are not. We have changed the theory of damages. It is a price  
17 inflation theory. I can't put it as well as an established  
18 jurist like Judge Weinstein, so I am going to quote from Judge  
19 Weinstein in his Zyprexa opinion, which Mr. Cheffo opened the  
20 door to a few moments ago, which will put, I think, in stark  
21 relief precisely what our case is about.

22 And it works like this: This is an overpricing  
23 claim. It alleges a direct injury by third-party payers who  
24 are among the plaintiffs. They overpaid from their own funds  
25 because of the illegal, deceptive marketing practices of the

1 defendant in that case.

2 And he cites the Desiano case. Quote -- now I'm  
3 quoting -- based on expert reports and available modes of  
4 economic analysis, a trier could determine that Zyprexa would  
5 have or would not have sold for a reasonably precise computable  
6 lesser amount than it was sold for were it not for Lily's  
7 fraud, period, close quote. That is the model now of this  
8 case.

9 Now, yes, is the word off-label present in the second  
10 amended complaint? Yes, it is. Is off-label marketing a  
11 component of over promotion? Yes, it is. We don't hide from  
12 that. We don't run from that. But we do not seek damages on  
13 off-label prescriptions qua, q-u-a, off-label prescriptions.  
14 That cannot be done without undue burden. That's point number  
15 one.

16 How would you show off-label prescriptions? That gets  
17 me to the next point. That is the kind of data that one does  
18 have from the IMS Health and Verispan of the world. It shows  
19 the total number of prescriptions. It can show the total  
20 number of prescriptions for certain patient constituencies with  
21 certain lipid profiles. And, therefore, you can at least get a  
22 numerical understanding that a doctor and an econometric expert  
23 can understand of where the prescriptions are growing. Are  
24 they growing in the folks who fit the profile under the  
25 guidelines making it on-label or are they outside of the

1 guidelines making it off-label?

2 And because, and this is important, we're not seeking  
3 damages for those prescriptions as those prescriptions, but  
4 simply in terms of the effect they have on price, we don't need  
5 to go down the road of identifying every single one of them.  
6 That kind of analysis by an expert suffices for purposes of  
7 liability.

8 Mr. Cheffo says, well, then, wait a minute, that means  
9 it is relevant, it is part of the liability side of the case.

10 Brings me to another point. Whose medical records are  
11 these? They are not ours. We do not possess them. We never  
12 did. They are not in our care, and they are not in our  
13 custody, and they are certainly not in our control.

14 Let me talk about this for a moment because it is  
15 important. A little context. When we started this case we  
16 alleged that the off-label prescription theory, which led us  
17 into this (unintelligible) of questions and issues about  
18 getting these individual medical records, we didn't possess  
19 those records then. But as your Honor ruled, they were  
20 relevant to the way we were seeking to prove our case. And  
21 Pfizer you ruled defensibly, arguably, correctly, that, yes,  
22 they are entitled to get behind that. That's a fair fight.  
23 That's where we were. We couldn't live with that.

24 By changing the theory we have now mooted the question  
25 whether we as plaintiffs have to go get documents that are

1 still not in our care, custody or control, and they are now not  
2 relevant to the theory of damages. And any relevance they have  
3 to the case is seriously outweighed by the burden of getting  
4 them.

5 Let's talk about that burden. Number one, we don't  
6 have them. All the lists that Mr. Cheffo submits in his  
7 memorandum of law to the Court, notwithstanding, we do not have  
8 them. It is exactly the same. It is when I go to my database  
9 with all the Pfizer documents and type in forecasts, budgeting  
10 forecasts, market surveys, I get nothing.

11 And the answer to that is, Mr. Cheffo told me, we  
12 don't keep those documents in that way. I asked for them.  
13 They said they don't have them. End of story.

14 There is any number of documents they have asked for  
15 from us that we simply do not have. We certainly don't have  
16 documents that respond to a third party's medical records.  
17 That's what they have. We don't have them.

18 Now Mr. Cheffo says, well, wait, you have got control  
19 over them. That is not so. HIPAA, HIPAA regulates the  
20 disclosure of personal medical information, but in an important  
21 way it sets a floor. Not a ceiling; a floor. HIPAA expressly  
22 states that it does not preempt state laws that are more  
23 restrictive of disclosure, state laws that are more restrictive  
24 of disclosure.

25 And you say, well, that's interesting, Mr. Grygiel,

1 but what does it matter? It matters this way, your Honor.  
2 That deals with control. We don't have control over documents  
3 where a third party is not permitted to give them up even if a  
4 plan document says we think we're entitled to them for whatever  
5 purpose. It doesn't work that way.

6 But that's just me being general. Why don't we take a  
7 look specifically and see if we can take a look at these HIPAA  
8 provisions because we have got a couple of funds here, as  
9 Mr. Cheffo points out. Let's talk about them.

10 Well, first we have got the Illinois fund.

11 THE COURT: Well, what are you looking at?

12 MR. GRYGIEL: Pardon me, your Honor?

13 THE COURT: What document are you looking at?

14 MR. GRYGIEL: I'm simply looking at my notes for the  
15 moment.

16 THE COURT: Oh, okay.

17 MR. GRYGIEL: Simply midpoint in our briefs about  
18 HIPAA, and Mr. Cheffo attacked them. I think it is fairly  
19 before the Court.

20 THE COURT: I thought you were looking -- turning to  
21 an exhibit.

22 MR. GRYGIEL: No, your Honor. Sorry. I don't come as  
23 fully loaded with exhibits as my counterparts.

24 Illinois case, National Abortion Federation versus  
25 Ashcroft. We cited it. 2004 Westlaw 292079, Star pages 2 and

1 4.

2 Chief Justice Kocoras, quote, because we find an  
3 Illinois law is more stringent than HIPAA's disclosure  
4 requirements and that it would be impossible for  
5 Northwestern -- I note parenthetically a hospital -- to comply  
6 with both Judge Casey's HIPAA pursuant order and various  
7 provisions of Illinois law, Illinois's non-party -- important  
8 point for us -- non-party patient privacy laws are not  
9 preempted by HIPAA and its subsequent regulations.  
10 Accordingly, the Judge ruled, Northwestern, the hospital, did  
11 not have to disclose the personal medical information that had  
12 been requested. And --

13 THE COURT: You know that decision was --

14 MR. GRYGIEL: Yeah.

15 THE COURT: -- reversed by the Seventh Circuit.

16 MR. GRYGIEL: But it wasn't on that ground, your  
17 Honor.

18 THE COURT: It was on the ground that he didn't  
19 correctly apply the law. The state law did not apply. The  
20 state privileges did not apply in federal context.

21 MR. GRYGIEL: Right, your Honor.

22 THE COURT: It is federal -- a federal issue. Federal  
23 law looks to state and respects it when appropriate. But you  
24 have to be -- take great care in citing Judge Kocoras's  
25 decision because of the change in that ruling. And I forget

1 whether the bottom line of the result changed or not. But they  
2 certainly didn't approve of all of the rationale by Judge  
3 Kocoras.

4 MR. GRYGIEL: Not all the rationale.

5 But, your Honor, when you look then, as I did, at the  
6 actual Illinois statute on which Judge Kocoras made that  
7 rationale, based that rationale more accurately --

8 THE COURT: Uh-huh.

9 MR. GRYGIEL: -- 735 Section 5, Section 8 sub 302, it  
10 gives, I believe, 12 discrete categories where medical  
11 information can be released. And one of them includes the  
12 consent of the parties. The rest of them cite the other areas,  
13 other contexts, other issues in which it can be released  
14 without patient consent.

15 And, your Honor, without belaboring every single one  
16 of them, homicide, malpractice actions, boating injuries  
17 involving blood alcohol tests, automobile injuries involving  
18 blood alcohol tests, the Court gets the point --

19 THE COURT: Uh-huh.

20 MR. GRYGIEL: -- none of them apply here.

21 That being the case, they don't talk about the same  
22 kinds of things that HIPAA talks about. HIPAA would permit  
23 disclosure with a court order. This doesn't say that.  
24 Illinois is more stringent. HIPAA does not trump under  
25 Illinois law. And it seems quite clearly for our purposes

1 control is something that is lacking on the part of the  
2 plaintiff funds. These are the patients's information.

3 Now we go to Florida. You get the same analysis. The  
4 case there that's immediately relevant is Lemieux vest Tandem  
5 Healthcare of Florida, 862 S.2d. 745. Florida's substantive  
6 disclosure rights are more stringent than HIPAA's. And HIPAA  
7 preempts only less stringent disclosure laws, citing Florida  
8 statute 456.057.

9 That's three Illinois funds and one Florida fund that  
10 have the HIPAA problem means we don't have control over those  
11 documents.

12 The New York fund, In Re Antonia E., 838 NYS.2d. 892,  
13 894, 898. It cites the Ashcroft case -- and this is a recent  
14 case actually. It was June 25, '07 -- saying New York's more  
15 rigorous disclosure laws control, HIPAA does not.

16 Same for the Texas statute when you look at it.  
17 Section 81.103 standing for the (unintelligible) fund.

18 Your Honor, the point is we don't have control of  
19 these documents. So asking us to produce them is asking us to  
20 produce something that does not -- we argue is irrelevant or at  
21 best marginally relevant and can be shown otherwise so that  
22 Pfizer can make the argument that it is utterly defenseless in  
23 terms of time to prove their defenses, but it is stuff that we  
24 just don't have.

25 Now Pfizer said, well, wait, progress says it is

1 unduly burdensome. He has made this point a lot. Doesn't he  
2 have to give you something more than that?

3 Well, your Honor, I'm not sure that they do. I read  
4 one of your Honor's opinions, and that was one of the cases  
5 they cited. And that is the Patterson versus Burge case. And  
6 in the second iteration of that case, not the May 4 case that  
7 the plaintiff cites, your Honor says that Rule 11(b) governs  
8 attorney's representations to the Court. I have made  
9 representations to this Court about the difficulty and  
10 burdensomeness of getting these non-party documents. I stand  
11 by those.

12 And we have the Kucara case, K-u-c-a-r-a, in the  
13 Northern District of Illinois that also says in the discovery  
14 sanctions context that representations of counsel, plus in that  
15 case certain affidavits, can suffice for purposes of  
16 establishing the facts.

17 If we need an affidavit to show how much more  
18 burdensome this is, we can provide it to the Court. But I  
19 believe that that has already been something recognized by this  
20 Court. I think it is on page 31, I think, of the August 28  
21 transcript. I might get the wrong page and the wrong  
22 transcript, but I know your Honor said, I recognize,  
23 Mr. Grygiel, that you said this is burdensome. And I believe  
24 your Honor accepted that representation. It is a matter of  
25 documents.

1           So we start with that. That's prong one of their  
2 motion to compel. It is actually the fourth argument in their  
3 motion to compel, I think. And it is prong one of our motion  
4 about why we should be relieved of this burden. Summarizing,  
5 A, not relevant.

6           B, if relevant, outweighed by the burdensomeness.

7           C, Pfizer says, well, look, on the merits they can't  
8 win anyway. If there is no set of facts that they can show,  
9 whether it is price inflation, whether it is off-label  
10 marketing, whether it is early promotion of some different  
11 variant that would permit them to succeed. In that case I  
12 submit to your, that changes the difficulty, the relevance  
13 rationale, the balancing test that this Court employs in  
14 deciding whether or not something really ought to be produced.

15           In no set of facts, because these cases that  
16 Mr. Cheffo cites, Williams and the In Re The Operating  
17 Engineers of New Jersey case that just came down, if under no  
18 set of facts could be this proven, that suggests that the  
19 discovery, even if relevant, arguably relevant, is unduly  
20 burdensome because he's really saying as a legal matter it  
21 doesn't matter, we don't need it.

22           THE COURT: We're taking a break.

23           Recall the Randolph case for a moment.

24           (Whereupon the Court turned to other matters on her call:)

25           THE COURT: All right. I'm sorry.

1 Mr. Grygiel.

2 MR. GRYGIEL: Sure.

3 THE CLERK: 06 C 1818, Southern Illinois Laborers's  
4 Employers Health and Welfare Fund versus Pfizer.

5 THE COURT: Okay. Mr. Grygiel, you were continuing  
6 your argument.

7 MR. GRYGIEL: Okay.

8 Moving from the argument of relevance and moving from  
9 the argument of burden, as I would repeat, we'd be happy to  
10 provide an affidavit if that's necessary. Pfizer makes the  
11 argument in their papers, well, plaintiffs are really playing  
12 fast and loose with the Court because they are saying one thing  
13 to Judge Darrah and another thing to Judge Brown about just how  
14 this discovery works.

15 On that point, your Honor, I'll rest simply by saying  
16 this, the Court has said that the Court has read the  
17 transcripts. I can cite chapter and verse from those  
18 transcripts. We didn't say a single thing in those transcripts  
19 that is inconsistent, dishonest or otherwise a fraud on this  
20 Court. We take the implication of that very seriously and  
21 believe it is totally unwarranted.

22 What we told this Court when we were told you may have  
23 the opportunity to file a second amended complaint and we got  
24 that opportunity and we filed it and we said most importantly  
25 for this argument, why, so we don't have to do this

1 individualized discovery. It was Pfizer who said to this  
2 Court, Judge, it is all the same stuff because that's what  
3 Pfizer needed to say then so they could keep the discovery  
4 going that they want us to do, discovery that we say is now  
5 irrelevant.

6 I mean, the argument they make about this being an  
7 unwarranted motion for reconsideration, well, frankly, your  
8 Honor, that seems to me a matter of semantics. The Court  
9 invited us to file a motion and said if we wanted relief --  
10 invited is too strong a word. The Court said if you want  
11 relief from our standing order, you better file something.  
12 That's what we did.

13 We're not saying, Judge, reconsider based on new  
14 authority, reconsider we think this case wasn't properly  
15 attended to or we think the Court's reasoning was improper and  
16 this reason. We're not saying that at all. We're saying  
17 circumstances changed pretty dramatically. Judge Darrah, a  
18 different agent, granted us leave to file a second amended  
19 complaint that alleges a new theory.

20 This isn't a motion for reconsideration. It is a  
21 motion to stop discovery that's both unnecessary and terribly  
22 burdensome, and it is for discovery that we don't even control.

23 On the argument that, well, Judge, they are asking for  
24 exactly the same stuff. It seems to me that some of the  
25 language there is tricky. But really what is going on here is

1 this: Yes, we have said to Pfizer we would like you to produce  
2 the kinds of data that shows to whom these prescriptions are  
3 being marketed so that we can show trends, so that we can show  
4 the market sectors where Pfizer's Lipitor drug was progressing  
5 or not progressing. And we know the habit, because I have  
6 called up the health providers who say, yeah, Pfizer buys a ton  
7 of this stuff from us. I have been told that it is coming. I  
8 have been told that for a long time, but I'm told it is coming,  
9 and I accept that in good faith. We bought some of it on our  
10 own.

11 This is not, your Honor, medical records. Mr. Cheffo  
12 said they are asking -- and he used the words, the same thing.  
13 That's not so. They are asking for us to get personal medical  
14 information from non-parties. We are asking them for data,  
15 number one, that they, a party, have. And they have  
16 acknowledged having it. It is a question of, as Mr. Cheffo  
17 says in his papers, reviewing it and producing it. That's  
18 number one. That's a big difference.

19 Number two, they are different kinds of data. We are  
20 looking for these surveys, your Honor. These don't give  
21 patient names, patient histories, patient notes about trouble  
22 with my family, my kids are driving me nuts, I'm afraid my wife  
23 is drinking too much, and personal medical records. This is  
24 different. These are numbers. These are something that an  
25 expert looks at and says, oh, I see this trend and explains it

1 to someone like me. That's what this is. It is comparing  
2 apples to oranges. The argument that Pfizer makes, that I  
3 think is largely an argument by false analogy.

4 But the most important thing is, even if we ask them  
5 for them, they have it. They are a party. They are asking us  
6 to get it from non-parties who are not litigants and don't have  
7 a direct interest in the case. That's a very different thing.

8 We're asking for commercially available, highly useful  
9 data that Pfizer uses in making its own business decisions.

10 THE COURT: Well, let me ask this question. When you  
11 get to the trier of fact, if you do, the jury in this case,  
12 clearly you won't be able to put before the trier of fact any  
13 information that is not produced by the plaintiffs in  
14 discovery. Rule 37(c) would preclude you from attempting at a  
15 later point to bring in any medical information about the  
16 people governed by the plans for whom Lipitor was prescribed or  
17 to hold up as an example John Jones, here's somebody, and  
18 here's plaintiff fund is in effect an insurer, and it paid a  
19 lot of money in Lipitor prescriptions improperly, if you don't  
20 provide that information in discovery.

21 MR. GRYGIEL: Absolutely right, your Honor. And we  
22 don't plan to prove the case that way, and we realize we  
23 couldn't.

24 Now there are obviously certain documents that we will  
25 be putting before the jury that aren't produced in discovery,

1 just like Pfizer will, just like these poster boards right here  
2 they are exhibits, but of course they will be premarked and  
3 what have you. But do we plan to base any exhibits or  
4 introduce anything in front of this jury that we haven't  
5 produced? Absolutely not. We understand that obligation.

6 And that does change the nature of the case because  
7 really what this does, to borrow again from Judge Weinstein who  
8 seems to be my favorite judge in this matter, is to say, you're  
9 going on this basis with an expert testimony based on data. A  
10 trier of fact could reasonably find that.

11 Now Pfizer says, well, does that -- that leaves us  
12 defenseless. Our argument to that, well, what's relevant for  
13 today's hearings, is, no, it doesn't. You have got that  
14 yourself. You have got the opportunity to hire your own  
15 experts.

16 Mr. Cheffo talked about how he would use the three  
17 months of expert witness discovery. They are going to attack  
18 it just that way, the same way we're putting it together. I  
19 understand that, your Honor. We're not going to be putting  
20 this stuff in individually. This isn't about hide the ball.

21 THE COURT: No, I don't mean individually, I mean even  
22 generalized. I, mean you can't make a generalized argument  
23 then that anyone was actually damaged by paying -- by paying  
24 more for a Lipitor prescription that was improperly  
25 prescribed. You couldn't then make that argument because you

1 wouldn't know whether any was actually improperly prescribed.

2 MR. GRYGIEL: Well, again, your Honor, what we're  
3 talking about is not improperly prescribed in the sense of  
4 off-label Lipitor, we're talking about a continuum between a  
5 price effect and over promotion, which has three categories of  
6 which off-label is just one. The others are overstating the  
7 benefits or inventing benefits, underplaying risks or hiding  
8 risks.

9 There are three categories of over promotion. We  
10 allege those in the second amended complaint. And what we say  
11 is with the data, not individual data, but the data of how the  
12 drug progressed in the marketplace relative to its price, tied  
13 in in the way that event studies work with Pfizer's marketing  
14 campaign, we'll be able to show, based on testimony; that is,  
15 deposition testimony, based on affidavits, probably based on  
16 some of Pfizer's former sales representatives and the like, as  
17 well as from Pfizer's own internal documents, not the ones they  
18 gave out to the doctors theoretically, but the do not detail  
19 documents, that here's how Pfizer was seeking to increase the  
20 market.

21 And then -- and this is where a Court accepts this  
22 premise or it doesn't -- you have an expert saying, with that  
23 data and with economic analysis that withstands the rigor that  
24 Daubert requires, I can say that the price was affected in the  
25 following way. And then you get the differential, as Judge

1 Weinstein was talking about in his Zyprexa opinion between what  
2 the parties would have been without the over promotion and what  
3 the price actually in fact was. That's how the case would be  
4 proven.

5 That, your Honor, doesn't rely on John Jones's medical  
6 records, to use the Court's example, but rather on the expert's  
7 fair basis based on all of the data gathered. Obviously we  
8 want Pfizer's data because that deals with Pfizer's  
9 understanding of what the market was. That would help  
10 corroborate our own expert's analysis.

11 THE COURT: Okay. The next point, and I do have a  
12 couple more cases coming in so -- and I do need to deal with  
13 another -- another motion that is on the list.

14 So how much more do you have, Mr. Grygiel?

15 MR. GRYGIEL: I can sit down right now, your Honor,  
16 and let Mr. Cheffo speak.

17 THE COURT: Okay. Let me take a short break before  
18 you, Mr. Cheffo --

19 MR. CHEFFO: Yes, your Honor.

20 THE COURT: -- and call the Bakal case.

21 (Whereupon the Court turned to other matters on her call:)

22 THE COURT: Okay. Now let's resume now with  
23 Mr. Cheffo.

24 THE CLERK: 06 C 1818, Southern Illinois Laborers's  
25 Employers Health and Welfare Fund versus Pfizer.

1 MR. CHEFFO: Your Honor, I'm going to try to be very  
2 brief because I think your Honor indicated earlier, and  
3 certainly I think it makes a lot of sense, there is a lot of  
4 information, most of what you have heard both of us talk about  
5 is in the papers. So to the extent that the Court is going to  
6 go back and read it, I'm just going to cover a few very brief  
7 points and then answer any questions that your Honor may have.

8 The first is there is the point that the plaintiffs  
9 keep saying that their goal was to limit discovery. Well, you  
10 know, that may have been their goal, but, again, you have to  
11 look at what the complaint actually still says. And it is  
12 completely different than what -- the representations we have  
13 heard.

14 Every one of the 11 plaintiffs still says during the  
15 class period -- this is directly from the complaint -- they  
16 paid for wrongly inflated prices for Lipitor -- it is paragraph  
17 17 -- and for an increased number of Lipitor prescriptions  
18 generated through Pfizer's illegal marketing campaign. So they  
19 paid a higher price, and they paid for more. They keep saying  
20 we're not seeking damages for off-label prescriptions, but that  
21 is at least 15 or 20 times in their complaint.

22 They also say at page 5 of their opposition, rather  
23 the second amended complaint alleges that Pfizer's off-label or  
24 fraudulent marketing drove demand up and increased the price of  
25 Lipitor. So again their claim is two things, drove up demand,

1 we paid more for it, and also that it increased the price.

2           What the plaintiffs are trying to do is basically say,  
3 we have had a new damages theory, and the -- and Pfizer should  
4 be bound by it, not only for purposes of damages, but also for  
5 discovery and for liability. And that's -- there is certainly  
6 no support for that. We certainly don't adopt it. And,  
7 frankly, as I indicated earlier, Judge Weinstein is the one  
8 judge who has even allowed the price inflation theory. There  
9 has probably been a dozen judges who have rejected it. And  
10 even Judge Weinstein did not preclude discovery on these  
11 issues.

12           We have heard a lot about burden, burden, burden. But  
13 the law is very clear, as your Honor knows, all we have heard  
14 is the burden that may be upon the plaintiffs's attorneys. We  
15 haven't seen anything from the funds saying this is burdensome  
16 for the fund, no affidavits, nothing in the record, no support  
17 whatsoever. All we have heard is, I have to send out a lot of  
18 letters and some expert might have to actually view it. That's  
19 not what burden is about.

20           The -- and then your Honor probed Mr. Grygiel a few  
21 times. You know, what they are really asking for is they want  
22 us to produce, Pfizer to produce, tons and tons of documents,  
23 third parties to produce documents. They don't want to produce  
24 any documents. The only thing we're supposed to do is wait  
25 until discovery closes, and then at some point in the future

1 when their expert report comes out, they are going to have a  
2 statistical model. And at that point they say, well, all you  
3 can do is have your own expert on our playing field attack it.

4 Clearly that's not what the law provides. We don't  
5 feel this can be done in a statistical model. There is no  
6 class certified.

7 THE COURT: Well, let me ask Mr. Grygiel while he's  
8 here.

9 What do you mean by the allegation -- give me the  
10 paragraph, Mr. Cheffo -- about the increased number of  
11 prescriptions?

12 MR. CHEFFO: Yeah, that's paragraph 17. It is in the  
13 initial paragraph where they talk about every single fund,  
14 about their jurisdictional allegations.

15 THE COURT: Okay. But the increased number of  
16 prescriptions, what does that mean?

17 MR. GRYGIEL: Well, I know what the intent of it was,  
18 your Honor, is to say that the market was expanded by the  
19 over promotion. It was not intended to convey, and I can see  
20 it as I read it here, it does seem to.

21 MR. CHEFFO: Not to interrupt you, but there is also  
22 some --

23 THE COURT: Just a minute, Mr. Cheffo.

24 MR. CHEFFO: I'm sorry. No, go ahead.

25 MR. GRYGIEL: No, I don't mean to be rude, but --

1 MR. CHEFFO: No, go ahead, Steve.

2 THE COURT: No, go ahead.

3 MR. GRYGIEL: The answer is reading here I can see how  
4 it creates the impression, oh, yeah, we want money not only for  
5 more price, but for more off-label prescriptions.

6 Two quick points. Number one, that's inconsistent  
7 with the theory that we have alleged elsewhere in the  
8 complaint, which is the gravamen of the new complaint, as I  
9 have said to this Court and said downstairs, is standby price  
10 inflation; and, number two, the narrow focus we're saying that  
11 was, it was a way of showing that the actual market did  
12 increase, but that's not going to be the measure of damages.  
13 It is inartful, your Honor, I can concede that.

14 THE COURT: But isn't that a factual predicate to  
15 the -- the whole damage theory was that the market increased,  
16 the market -- in other words, people were buying more Lipitor  
17 that they would not be buying but for this off-label -- this  
18 improper marketing for off-label purposes? Isn't that the  
19 actual predicate?

20 MR. GRYGIEL: Your Honor, that's an important point,  
21 your Honor. It is factually important. I wouldn't go so far  
22 as to say it is a factual predicate. It is part of the chain  
23 of analysis that we believe is proper within the ken of an  
24 expert's testimony to show that, yes, demand was increased  
25 because the market was expanded. And a factor for showing that

1 the market was expanded was that Lipitor prescriptions, total  
2 prescriptions, key to Lipitor marketing campaigns, which  
3 include three categories of over promotion, resulted in more  
4 prescriptions being written. Yes.

5 Are we seeking damages for those that were one of the  
6 three categories off-label? No.

7 Is the fact that the market was increased by X number  
8 of, in this case, off-label prescriptions particularly relevant  
9 or even necessarily relevant to an expert's testimony here?  
10 No.

11 It is simply we can observe that the market increased  
12 in correlation with this variant of over promotion. That is  
13 illegal, improper otherwise. Leave that to the lawyers.

14 But that's the theory there, your Honor. But we're  
15 not saying the market went up by 17 percent. And of those 17  
16 percent, 255 were for off-label prescriptions. A, it would be  
17 very difficult to do credibly; and, B, that's not what our  
18 theory is.

19 THE COURT: But isn't a piece of that to avoid the  
20 post hoc ergo propter hoc fallacy that there was in fact an  
21 increase in the number of prescriptions written?

22 MR. GRYGIEL: That's going to be part of an expert's  
23 testimony, yes, sure.

24 THE COURT: Okay. Well, what are the facts on which  
25 he's going to base that? Doesn't have to actually look and

1 find if there were prescriptions actually written for improper  
2 purposes for Lipitor?

3 MR. GRYGIEL: Sure. And he can do that. I can do  
4 that today, your Honor, because I have, I think sufficient to  
5 satisfy a Daubert motion, I went out and spent \$16,000 on this  
6 data, had an expert look at it. And what the expert tells me  
7 is I can see that the amount of Lipitor written for people who  
8 are not unhealthy from a cholesterol perspective within the  
9 guideline parameters, and therefore Lipitor's label, increased  
10 over time. And of those it makes no statistical sense  
11 whatsoever to think that every single one of those was for some  
12 other medically warranted reason based on the fact that some  
13 doctor decided it.

14 THE COURT: Well, what's the factual predicate for  
15 that?

16 MR. GRYGIEL: Well, the factual predicate for that,  
17 your Honor, is that it is data that is observed in the  
18 marketplace by the compilers of this data on whom Pfizer itself  
19 arrives to make multi-million dollar marketing decisions. That  
20 data is re-writable. It comes from pharmacies who the data  
21 gets collected by two big sources, IMS and Verispan. And then  
22 they don't use all the data. They run algorithms, which Pfizer  
23 obviously trusts because Pfizer uses it. That's what the  
24 attachment, unfortunately unstapled to your Honor, showed, how  
25 Pfizer goes about getting this kind of information.

1           It is an important point, your Honor, and I don't seek  
2 to dismiss it, I don't seek to minimize it. It is part of the  
3 factual (unintelligible) that an expert will have to consider,  
4 but it is not going to be precisely numerical. It probably  
5 couldn't be. But it can be strongly factually based on the  
6 same kinds of evidence, to answer your question, that Pfizer  
7 itself uses based on commercially available data. We'll get it  
8 from the sources, and we hope to get it from Pfizer if we can.

9           If we don't, I'll get it from these sources. I have  
10 already subpoenaed them, and I have already paid for it.

11           THE COURT: Okay. Mr. Cheffo.

12           Thank you, Mr. Grygiel.

13           MR. CHEFFO: Your Honor, I think you have just, you  
14 know, heard probably better than I can say. I mean, they want  
15 it from us. It is relevant. But they don't want to have to  
16 produce it.

17           Paragraph 4 also says, of the complaint, this alleged  
18 off-label marketing resulted in unofficially increased number  
19 of Lipitor prescriptions for which the funds were required to  
20 pay. Artificially increased number which (unintelligible) had  
21 to pay.

22           So Mr. Grygiel is telling us we are, at some point  
23 after discovery closes, we're going to get an undisclosed  
24 expert's opinion based on information they don't want to share  
25 with us and haven't shared with us. And (unintelligible) 11

1 funds. There is going to be some statistical model of a  
2 national basis, but -- but I am certainly not allowed during  
3 discovery to even ask the funds, well, what about you? You are  
4 saying you had some -- I think he has told us before that there  
5 is some -- and I don't mean to personalize it -- Mr. Grygiel  
6 has told us before that there is some naturally occurring level  
7 of off-label prescriptions. He accepts that.

8 So our -- what we're trying to find out is your claim,  
9 both for damages and for liability, is that something bad that  
10 Pfizer did, increased that naturally occurring level of  
11 off-label prescriptions? That's what we're trying to find out,  
12 of the 11 funds who are actually the plaintiffs in the case.  
13 And the answer is, well, no, no, no, that's not relevant,  
14 that's a tiny microcosm, a minuscule section, I think they tell  
15 us. What we really need to do is go to a national statistical  
16 model basis.

17 So ultimately -- again, what's before this Court is  
18 not whether their model works, doesn't work, whether Judge  
19 Darrah or this Court will determine if it meets Daubert  
20 scrutiny. What is appropriate is whether this information is  
21 relevant. And we have heard counsel just tell us, of course,  
22 it is relevant, they don't just don't like the format.

23 Now the only thing that -- (unintelligible) to find,  
24 and I'm going to call their Patient Number 3 -- and I'm really  
25 going to wrap up in a second urging.

1           They identified, I think, four people they said were  
2 off-label and two that might have been. Do you remember that  
3 in connection with --

4           THE COURT: Yes.

5           MR. CHEFFO: We went out and actually -- we'll call it  
6 Patient Number 3. Patient Number 3 voluntarily gave us an  
7 affidavit saying she is elderly, overweight, she has  
8 pre-diagnosis -- pre-diabetes, she has triglyceride levels, her  
9 brother died of a heart attack at age 41, her father died of a  
10 heart attack -- this is already in the papers -- early. And  
11 she basically says, I believe that my doctor prescribed Lipitor  
12 because he actually evaluated my health characteristics, my  
13 family history, and other factors, and I relied on him.

14           So that's going to be -- and that's exactly the kind  
15 of evidence that shows -- remember four -- and just the one  
16 person who came forward and said, of course I don't think that  
17 my doctor prescribed this based on some marketing message, I  
18 think that my doctor did the right thing because he cares about  
19 my health. And that's the kind of information that they are  
20 seeking to prevent us.

21           Now let me talk for one minute about control. They  
22 say, well, we have no control over this. But you'll recall the  
23 three-page letter that they sent to every doctor in Florida.  
24 In that letter they said, not to worry about HIPAA, you have a  
25 right to produce this. And we know tons of doctors did produce

1 it because that's how they got the four patients. That was  
2 without an authorization.

3 So, one, they have told the doctors, they have told  
4 other people, we have the ability to get this. They don't plan  
5 documents. That's all in our papers. Specifically say that we  
6 as the insurer -- they're essentially an insurance company --  
7 have a right to request medical information if we are seeking  
8 reimbursement or payment for a claim made on your behalf.  
9 Every fund has that language. And if that doesn't get to you  
10 control, I don't know what does.

11 With respect to this HIPAA argument, one, again, there  
12 is nothing in the record that any doctor said, well, I'll  
13 comply with HIPAA but not some state rule. And I think the  
14 Court correctly pointed out there is a Seventh Circuit case  
15 that basically says, the Legianne (phonetic) case or -- I  
16 believe it is, and it is in our papers, that basically says, we  
17 have a federal question, HIPAA trumps any -- any state law  
18 claims. So that's a non-issue.

19 The last thing that I would like to tell you is I just  
20 blew up this one paragraph from their reply that I think sums  
21 it all up here. They say --

22 Can you see, Steve?

23 MR. GRYGIEL: Thanks.

24 MR. CHEFFO: -- Pfizer's argument for individualized  
25 discovery, the plaintiffs must show that each prescribing

1 doctor was influenced by Pfizer's over promotion is wrong.

2 Pfizer's predicate for that argument is that  
3 prescribing doctors exercise independent medical judgment as  
4 (unintelligible) to be intermediaries. Were that true and  
5 doctors exercised completely independent medical judgment  
6 impervious to Pfizer's marketing blandishments, Pfizer would  
7 not spend millions detailing Lipitor to doctors.

8 So what does that mean? That means that the Court  
9 should as a matter of law prevent us from having any discovery  
10 because as a matter of law all doctors are improperly  
11 influenced by Pfizer's promotion. Why? Because Pfizer spends  
12 money on advertising.

13 Now obviously it is ridiculous, but that's -- that's  
14 the basis of what they are arguing and have been arguing. And  
15 I think that when the Court has an opportunity to look through  
16 the papers, and certainly we would make ourselves fully  
17 available if you have any additional questions after reading  
18 them, but I think when you look at it from the perspective of  
19 is this relevant and is there any burden on the parties that  
20 count, the actual parties in the case, and is there anything in  
21 the record to support that, I think you'll find that it is  
22 certainly relevant as they admit, and there is really no more  
23 burden, certainly, than what Pfizer has been put through in  
24 producing half a million pages of documents when they have  
25 produced -- most of them have produced about 150 pages.

1 THE COURT: One -- one short argument from  
2 Mr. Grygiel.

3 But first I'm going to ask --

4 MR. CHEFFO: Yes, your Honor.

5 THE COURT: -- (unintelligible).

6 Your motion to compel the information about the people  
7 who leaked, so to speak --

8 MR. CHEFFO: Yes.

9 THE COURT: -- the documents, how do you respond to  
10 Mr. Cheffo's -- or Mr. Grygiel's arguments about the  
11 confidentiality?

12 MR. CHEFFO: Very quickly.

13 THE COURT: Yeah.

14 MR. CHEFFO: I think that the case -- you know, the  
15 evidence for the first time that they had ever even indicated  
16 that it was an attorney witness was in the -- in their  
17 opposition papers. So we move, say, you have attached  
18 these -- many of these papers -- these documents to your  
19 pleadings, you have produced them during discovery. We want --  
20 and you have also talked about reliance and all different kinds  
21 of RICO claims. We want to have an understanding of where you  
22 got these documents because clearly they are internal, stolen  
23 Pfizer documents. They just objected on work product.

24 And we also sent them interrogatories and admissions  
25 saying, does each one of the funds have the documents? They

1 say yes.

2 So I think we're entitled to find out when -- just  
3 fact questions, when they were produced, who got them. So in  
4 other words, if they -- if the funds didn't get them until  
5 after the complaint was filed, well, that will assist us in  
6 depositions. But we can't -- we won't have to worry about when  
7 they relied upon, if they were relied upon. We didn't ask for  
8 internal notes between counsel and any interview. We basically  
9 just said, the fund is a plaintiff. You have these documents  
10 in your possession. You put them into play by, one, producing  
11 them to us, and also relying on this. So certainly there -- it  
12 is no different than any other document about asking fact based  
13 questions about how you got them.

14 And the final point is clearly because of the nature  
15 of these documents, they are highly confidential. They appear  
16 to at least go to the types of claims that plaintiffs are  
17 making. The person who had that document or persons and their  
18 involvement would be a possibility or a probability a witness  
19 in this case.

20 So the who, what, where, and when questions, I think,  
21 are absolutely appropriate. They are relevant. And they  
22 don't -- it is kind of a two trains passing in the night.  
23 We're not asking for any internal Grant & Eisenhower work  
24 product information, we're just asking the funds, you have the  
25 information, you relied on it in your complaint, tell us where

1 you got it, who gave it to you, and what were the circumstances  
2 that you received it.

3 THE COURT: All right. Briefly, because I have  
4 another case.

5 MR. GRYGIEL: Briefly addressing that point, your  
6 Honor, the cases that Pfizer cites for purposes of saying turn  
7 it over, I'll say take two. One is your Honor's case,  
8 Patterson versus Burge. The other case is the Teleflora case.  
9 In both of those cases what was at issue were facts held by  
10 someone whose identity was either not disclosed, that's the  
11 Burge's case, an alibi witness, or in the Teleflora case, it  
12 was a similar scenario.

13 Here the facts that are relevant to the good faith  
14 basis for bringing the complaint are contained in the documents  
15 themselves, 2250 pages. Two full boxes, CDs, and videotapes.  
16 They got turned over. That's what's relevant. That's what  
17 shows when you are asking those deposition questions what was  
18 the basis for bringing the complaint. We had these documents.

19 Who reviewed these documents? We did.

20 What's the importance of these documents? Well, it is  
21 this, it is this. It showed we were paying too much or  
22 whatever it is. Those are the relevant facts, not going out  
23 and heavy handedly trying to intimidate some witness who turned  
24 them over. That's an entirely different kettle of fish.

25 The relevance in this, your Honor, is the relevance of

1 the facts and the document that relate to Pfizer's behavior,  
2 not to somebody's individual investigation of the case who then  
3 decided to turn those documents over.

4 One other quick point, your Honor, and then I'm done.  
5 Mr. Cheffo said, well, they can do it, it is not burdensome,  
6 look at the Florida case, look at the letters. Yes, indeed  
7 those letters said we have the ability to do this, to get these  
8 documents. And a lot of doctors's offices called and said, no,  
9 you don't. That's number one.

10 Number two, I got calls from lawyers. I got the calls  
11 from the lawyers. And the lawyers said, read HIPAA, pal,  
12 Florida law controls, not HIPAA. Florida is more restrictive,  
13 you don't get them. I'll give the Court an affidavit if the  
14 Court wants one on that. That is what happened there.

15 Mr. Cheffo used the word tons. It wasn't tons. I  
16 think we got 50. There were a lot more people who took  
17 Lipitor. That's what we got there.

18 And, finally, your Honor, they cite a case In Re  
19 Operating Engineers of New Jersey. It is a Supreme Court New  
20 Jersey case. Just came out September 7, 2007, saying, no  
21 thanks to class certification under the Court's inflation  
22 theory. Pfizer loves it. Understandably they love it.

23 But the point I'm citing that case for is this: It  
24 has got a terrific description of how third-party payers  
25 operate, and what they do in terms of processing claims. And

1 why so many of the documents that Pfizer is saying we haven't  
2 turned over haven't been turned over, it is because we don't  
3 have them. That's not what we do.

4 Their very case makes the process quite clear. It  
5 (unintelligible) it in very conspicuous and stark relief. We  
6 don't collect those documents. That's the point. We don't  
7 have them.

8 And one -- and finally, your Honor, one other thing.  
9 There is always one other thing I know, and I'm talking too  
10 much, and it is this: Plaintiffs have indeed exchanged a  
11 large -- communications, not so many letters, I'm not quite as  
12 fastidious to correspond that some others are, about document  
13 production. Pfizer has produced a lot of pages of documents.  
14 But, your Honor, they came late. Admittedly, so did ours.  
15 They came late. They are almost entirely within one category  
16 of documents, marketing documents, with innumerable  
17 duplications of textbooks and of similar other backups for  
18 advertising claims.

19 So it is not as if Pfizer's document production has  
20 been responsive to any number of the narrow focused categories  
21 that we have raised. They have either been told to me that  
22 they don't exist or that they are being looked at.

23 But it is really, to be fair, I'm not looking to cast  
24 aspersions, but to say hundreds of thousands of pages of  
25 documents makes it look like Pfizer did something truly

1 outstanding here.

2 What happened was our associates went over, looked at  
3 a whole bunch of documents Pfizer had laid out. Our guy said,  
4 copy them all, back they came. It is really a bunch of  
5 categories of documents.

6 THE COURT: Okay. Okay. Well, what I want to do, as  
7 I indicated earlier, is to take these, consider what arguments  
8 you have made today, pointing out -- highlighting some of your  
9 arguments. I anticipate getting a bound copy of what the  
10 plaintiff submitted as its reply.

11 MR. GRYGIEL: You will, your Honor.

12 THE COURT: And then if need be, call you back for  
13 further argument, answering questions. If not, I think the  
14 best thing to do would be to write something that then whatever  
15 results can be the subject of an appeal, if need be, to Judge  
16 Darrah.

17 All right. With that then, I'm going to take the two  
18 motions under advisement, and I'm not going to set a further  
19 date in this case.

20 If there is anything else you need to bring a motion  
21 on, you will --

22 MR. GRYGIEL: Thank you, your Honor.

23 MR. CHEFFO: Thank you, your Honor.

24 THE COURT: -- bring a motion.

25 So two motions -- motion hearing held on the

1 plaintiffs's motion -- defendant's motion to compel, and  
2 plaintiffs's motion to modify discovery. The motions are taken  
3 under advisement.

4 The Court will issue a ruling by mail.

5 MR. GRYGIEL: Thank you, your Honor.

6 THE COURT: Okay?

7 MR. CHEFFO: Thank you, your Honor.

8 (Which concluded the proceedings in the above-entitled  
9 matter.)

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C E R T I F I C A T E

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I hereby certify that the foregoing is a transcript of  
proceedings before the Honorable Geraldine Soat Brown on  
September 26, 2007.

DATED: October 3, 2007



# **EXHIBIT O**

**UNITED STATES DISTRICT COURT  
FOR THE Northern District of Illinois – CM/ECF LIVE, Ver 3.0  
Eastern Division**

Southern Illinois Laborers' and Employers Health and  
Welfare Fund, et al.

Plaintiff,

v.

Case No.:  
1:06-cv-01818  
Honorable John W.  
Darrah

Pfizer Inc.

Defendant.

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**NOTIFICATION OF DOCKET ENTRY**

This docket entry was made by the Clerk on Friday, December 14, 2007:

MINUTE entry before Judge Geraldine Soat Brown :Parties' joint motion for stay of Magistrate Judge's 11/14/07 memorandum opinion and order [177] is granted. Plaintiffs' compliance with this Court's Order of 11/14/07 is stayed until ten days after the District Court's final ruling on the plaintiffs' objections to that order. However, the parties are advised that the references in their motion to "Magistrate" and "Magistrate's Order" are incorrect. There have been no federal "magistrates" since 1990. The proper title is "Magistrate Judge." 28 U.S.C. § 631. Motion hearing set for 12/19/07 is stricken. Notice mailed by judge's staff (ntf, )

**ATTENTION:** This notice is being sent pursuant to Rule 77(d) of the Federal Rules of Civil Procedure or Rule 49(c) of the Federal Rules of Criminal Procedure. It was generated by CM/ECF, the automated docketing system used to maintain the civil and criminal dockets of this District. If a minute order or other document is enclosed, please refer to it for additional information.

For scheduled events, motion practices, recent opinions and other information, visit our web site at [www.ilnd.uscourts.gov](http://www.ilnd.uscourts.gov).

# **EXHIBIT P**

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

SOUTHERN ILLINOIS LABORERS' AND	)	
EMPLOYERS HEALTH AND WELFARE	)	
FUND; NECA-IBEW WELFARE TRUST	)	
FUND; MIDWESTERN TEAMSTERS	)	
HEALTH AND WELFARE FUND; THE	)	
WELFARE FUND OF TEAMSTERS	)	
LOCAL UNION 863; PLUMBERS AND	)	CIVIL ACTION No. 06-CV-1818
PIPEFITTERS LOCAL UNION 630	)	
WELFARE TRUST FUND; CLEVELAND	)	JUDGE JOHN W. DARRAH
BAKERS AND TEAMSTERS HEALTH	)	
AND WELFARE FUND; ELECTRICAL	)	MAGISTRATE JUDGE
WORKERS BENEFIT TRUST FUND; FIRE	)	GERALDINE SOAT BROWN
& POLICE RETIREE HEALTH CARE	)	
FUND, SAN ANTONIO; LABORERS'	)	
DISTRICT COUNCIL BUILDING AND	)	
CONSTRUCTION HEALTH AND	)	
WELFARE FUND; LABORERS'	)	
DISTRICT COUNCIL HEAVY AND	)	
HIGHWAY UTILITY HEALTH AND	)	
WELFARE FUND; and NEW YORK CITY	)	
POLICE SERGEANTS BENEVOLENT	)	
ASSOCIATION HEALTH & WELFARE	)	
FUNDS, individually, and on behalf of all	)	
others similarly situated,	)	
Plaintiffs,	)	
v.	)	
PFIZER INC.,	)	
Defendant.	)	
	)	

**PLAINTIFFS' AMENDED OBJECTIONS TO MAGISTRATE BROWN'S ORDER DATED  
NOVEMBER 14, 2007 DENYING PLAINTIFFS' MOTION TO MODIFY DISCOVERY**

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Plaintiffs file this Objection to Magistrate Brown's Memorandum Opinion and Order dated November 14, 2007, denying Plaintiffs' motion seeking modification of discovery pursuant to Fed. R. Civ. P. 72(a) (the "Order").<sup>1</sup>

### INTRODUCTION

On November 14, 2007, Magistrate Judge Soat Brown ordered Plaintiffs to contact hundreds of doctors across the country and to force them to turn over personal medical records of thousands of individual patients, under a reasoning that such information is "relevant," within the meaning of Rule 26, to establish a damages theory that *is no longer being asserted in this case*. Not only is the production of personal medical records of thousands of individuals – who are not even members of the class asserted in this case – highly intrusive, but the burden imposed on Plaintiffs to go out and obtain this information is exceptional and greatly outweighs any possible probative value that the records may have here. In considering this issue, it is important to keep in mind that Plaintiffs *do not have custody or control* over the medical records that are the subject of Magistrate Judge Soat Brown's Order. Rather, if the Order is upheld, the Plaintiffs would be forced to contact the physicians who cared for the patients who are beneficiaries of the health plans administered by Plaintiffs, and to request that they produce these individual medical records without the consent of the individual patients themselves. This extraordinary burden cannot be justified under Rule 26, particularly where the information that may be gleaned from individual patient records has no relevance whatsoever to the theory of damages articulated by the Plaintiffs or to any defense articulated by Pfizer. And in this regard, Magistrate Soat Brown's Order is clearly erroneous and contrary to law.

In the Second Amended Complaint (the "SAC"), the operative complaint at issue here, Plaintiffs allege that Pfizer Inc. ("Pfizer") engaged in a systemic illegal marketing campaign designed to artificially inflate the market for its blockbuster drug Lipitor, and that through the implementation of illegal marketing practices – which included but was not limited to illegal off-label marketing – Pfizer was able to artificially inflate the *price* it could charge for Lipitor. In stark contrast to the theory of damages alleged in the First Amended Complaint (the "FAC"), wherein Plaintiffs alleged that Pfizer illegal off-label marketing wrongfully increased the market for Lipitor by increasing the number of off-label prescriptions written for the drug, under the

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<sup>1</sup> Magistrate Brown's Memorandum Opinion and Order dated November 14, 2007 is attached hereto as Exhibit A.

theory articulated in the SAC, the number of off-label prescriptions for which the individual Plaintiffs may or may not have paid is completely beside the point. Indeed, whether a particular Lipitor prescription was written for on-label or off-label use is now completely irrelevant. Under Plaintiffs' damages theory articulated in the SAC, the relevant inquiry is the inflated price Plaintiffs and other third party payors were compelled to pay for *all Lipitor prescriptions*, regardless of their ultimate use. And, as discussed below, this theory of damages can be proved (and defended by Pfizer) entirely based on publicly available data, data obtained from third party market-survey companies (such as Verispan and IMS Health), and from information within Pfizer's possession (which it admits it has, but to date has refused to produce).

Because Plaintiffs do not seek damages based on the number of off-label prescriptions third party payors paid for, the individual medical records of patients who took Lipitor are simply not relevant to Plaintiffs' theory of damages asserted in the SAC. Similarly, there is absolutely no argument – and Pfizer has articulated none – that the information is somehow relevant to establishing any defense that Pfizer may have to the claims asserted in this case. Magistrate Judge Soat Brown's November 14 Order, therefore, simply cannot be justified under the applicable standards governing the production of documents under Rule 26 and must be vacated.

### **FACTUAL BACKGROUND**

Plaintiffs filed the FAC against Pfizer on December 11, 2006. In the FAC, as in the original complaint, Plaintiffs alleged that Pfizer illegally marketed its blockbuster statin Lipitor for off-label use, and that as a result Plaintiffs, and similarly situated third-party payors ("TPPs"), suffered damages by being forced to pay for an increased number of Lipitor prescriptions generated through Pfizer's illegal marketing. Plaintiffs intended to establish damages under this theory through the use of statistical modeling showing an increase in the number of Lipitor prescriptions caused by or attributable to Pfizer's illegal marketing practices. In response to this articulated theory, however, Pfizer served an interrogatory on Plaintiffs seeking identification of "each prescription of Lipitor for an off-label purpose as defined in the [FAC] . . . for which you paid or provided reimbursement." See e.g., Interrogatory No. 3 of Defendant Pfizer Inc.'s First Set of Interrogatories to Plaintiffs dated June 6, 2006 attached hereto as Exhibit B ("Interrogatory No. 3").

Based on the theory of liability pled in the FAC, Plaintiffs did not intend to prove damages based on payments made for individual off-label prescriptions, but rather by using internal Pfizer data demonstrating Pfizer's illegal off-label marketing efforts and statistical modeling establishing a relationship between Pfizer's illegal marketing and a corresponding increase in sales of Lipitor. On Pfizer's motion to compel responses to Interrogatory No. 3, Magistrate Judge Brown rejected Plaintiffs' proposed approach to establishing damages for purposes of discovery and on July 19, 2007, ordered that by August 20, 2007, Plaintiffs identify each allegedly off-label Lipitor prescription paid for by one of the funds to be selected by Plaintiffs. *See* Order at 2. Plaintiffs identified the Plumbers & Pipefitters Local Union 630 Welfare Trust Fund ("Plumbers & Pipefitters") as the test fund.

Plumbers & Pipefitters did not have the medical records that were the subject of the July 19 Order. Accordingly, to comply with the discovery ruling, Plumbers & Pipefitters engaged in an expedited and extraordinarily burdensome campaign to contact individual doctors and obtain the requested records from them. This process was very time consuming and laborious and often involved direct communications between Plaintiffs' counsel, Plumbers & Pipefitters, several of the Plumbers & Pipefitters' members and their physicians. Plaintiffs were repeatedly asked to explain the need for reviewing individual participant's medical histories and the nature of the information being sought. Moreover, in order to evaluate the necessary participant files, Plumbers & Pipefitters often was required to obtain medical records release authorizations from each of their Lipitor-taking participants prior to obtaining the necessary records.

Given the intrusive and time consuming nature of the review conducted for the Plumbers & Pipefitters fund, replicating this process for the remaining funds (let alone for all members of the class) simply was not realistic. Based on the burden imposed by proving damages under the theory articulated in the FAC (as interpreted by Judge Brown) on August 28, 2007, Plaintiffs sought leave to file a Second Amended Complaint ("SAC"). [Dkt 113.] The SAC, which was filed to avoid the burden imposed by Judge Brown's discovery rulings, completely changed Plaintiffs' theory of damages. Contrary to the FAC which premised liability on increased *sales* of Lipitor for off-label uses of the drug, the SAC pleads that Pfizer increased the *price* of Lipitor through a host of deceptive schemes which in turn caused Plaintiffs to pay artificially inflated prices for Lipitor regardless of its use. Thus, unlike the FAC, the SAC seeks recovery of payments for Lipitor regardless of whether the payments were for on-label or off-label uses.

While the motion for leave to file the SAC was pending, Magistrate Brown ordered Plaintiffs to provide the information provided by the Plumbers & Pipefitters for the remaining funds.

On September 3, 2007 this Court granted Plaintiffs' Motion for Leave to File the SAC, and entered a briefing schedule for Pfizer's motion to dismiss the SAC. [Dkt 126.] Plaintiffs filed the SAC the same day. As Plaintiffs' counsel described to the Court in a August 28, 2007 hearing before Magistrate Brown, the SAC greatly streamlines the case by simplifying Plaintiffs' theory of damages. *See* Order at 3. Put simply, the SAC now alleges only that Pfizer's false and misleading promotion of Lipitor resulted in Lipitor's price being higher than it would have been without such promotion. Damages under the SAC are, therefore, the difference between the price Plaintiffs paid for Lipitor and the price they would have paid had Lipitor's price not been wrongly inflated by Pfizer's false statements and material omissions. Whether or not TPPs paid for off-label prescriptions of Lipitor is now simply irrelevant to the theory of damages pled in the SAC. Given that the administrative burdens and privacy implications of this compelled discovery from the ten Funds now greatly outweigh any possible relevance that discovery might have, on September 10, 2007 Plaintiffs moved to modify the Court's August 28, 2007 order and sought a superseding order relieving Plaintiffs from the unnecessary burdens of obtaining, analyzing and producing thousands of medical records by September 26, 2007. [Dkt 136.]

As noted in Plaintiffs' papers seeking modification of Judge Brown's discovery rulings [Dkt 136], Plaintiffs intend to prove the theory pled in the SAC by using commercially available data, Pfizer's own documents produced in discovery, third-party documents, and *Daubert*-compliant econometric analysis and statistical modeling.

Under the operative complaint in this case (the SAC), Plaintiffs expressly do not seek damages for the *number* of off-label prescriptions they claim resulted from illegal off-label marketing. Instead, the Plaintiffs seek damages for the *dollar amount* by which Lipitor's price *was inflated* by Pfizer's false and misleading over-promotion of the drug. On November 14, 2007, Magistrate Brown issued the Order denying Plaintiffs' motion to modify discovery. The Order concluded that the identification of each off-label payment made by each fund was still within the scope of Rule 26 and that the production of such information was not overly burdensome. The Order also requires the production of the responsive information on a rolling basis with full compliance by December 21, 2007. The Order not only compels the Plaintiffs to obtain, analyze and produce highly personal medical information the Plaintiffs do not have and

must obtain from not necessarily amenable third parties, under a very short deadline during the holiday season, but to perform this extraordinarily burdensome work in service of a damages theory that Plaintiffs have affirmatively renounced and is not part of the SAC. Thus, the Order requires production of materials well outside the limits of Fed. R. Civ. P. 26(b)(1). The Order also requires Plaintiffs to incur a substantial burden to produce information that has minimal relevance to Plaintiffs' claims or Pfizer's defenses, a requirement that runs afoul of Fed. R. Civ. P. 26(b)(2)(C)(iii). Based on these violations of the Federal Rules, Plaintiffs respectfully ask this Court to sustain Plaintiffs' objections and relive Plaintiffs of their obligations under the Order.

### **ARGUMENT**

#### **MAGISTRATE BROWN'S NOVEMBER 14, 2007 ORDER MUST BE MODIFIED TO ACCOUNT FOR THE REVISED THEORY OF DAMAGES PLED IN THE SAC**

Fed. R. Civ. P. 72(a) provides "[w]ithin 10 days after being served with a copy of the magistrate judge's order, a party may serve and file objections to the order. . . . The district judge to whom the case is assigned shall consider such objections and shall modify or set aside any portion of the magistrate judge's order found to be clearly erroneous or contrary to law." "The 'clearly erroneous' standard applies to factual findings and discretionary decisions made in connection with non-dispositive pretrial discovery matters." *F.D.I.C. v. Fidelity & Deposit Co. of Maryland*, 196 F.R.D. 375, 378 (S.D. Cal. 2000). Where a magistrate's findings are based on legal conclusions and not findings of fact the "clearly erroneous standard does not apply" and the scope of review "is plenary." *See e.g., Jernryd v. Nilsson*, 117 F.R.D. 416, 417 (N.D. Ill. 1987). *See also Fidelity Deposit*, 196 F.R.D. at 378 ("The 'contrary to law' standard, however, permits independent review of purely legal determinations by the magistrate judge"). "[E]videntiary rulings typically pose questions of law, and discovery rulings that are dependent on evidentiary admissibility or likely admissibility do likewise." *Phillips v. Raymond Corp.*, 213 F.R.D. 521, 525 (N.D. Ill. 2003).

Here, the Order makes a legal determination that evidence of off-label payments remains discoverable under Rule 26(b)(1). The Order is therefore subject to plenary review. However, even if the deferential standard is applied to the Order, the burden imposed on Plaintiffs in responding to Magistrate Brown's ruling requires relief from the Order. *See National Union Fire Ins. Co. of Pittsburgh, Pa. v. Continental Ill. Corp.*, 116 F.R.D. 78, 85-86 (N.D. Ill. 1987) (reversing, as clearly erroneous, discovery order from magistrate requiring "expensive and time-

consuming” production). *See also Doe v. Aramark Educ. Res., Inc.*, 206 F.R.D. 459, 464 (M.D. Tenn. 2002) (reversing magistrate’s order requiring production of materials as beyond the scope of Rule 26(b)(1)).

**a. The Order Requires Production Of Materials That Are Not Within The Custody Or Control Of Plaintiffs**

As an initial matter, it is beyond dispute that Plaintiffs do not have custody of the personal medical records of the plan participants. Rather, the Order, if implemented, would require Plaintiffs to affirmatively go out and obtain these records from third parties – *i.e.*, the physicians who treated the plan participants as patients. Order at 7. As a simple matter of undisputed fact, therefore, Plaintiffs simply do not have “custody” of the documents they now have been ordered to produce. The relevant inquiry, therefore, turns on whether Plaintiffs have sufficient “control” over the medical records so as to require Plaintiffs to produce them. And in this regard, the practical realities are that Plaintiffs do not have sufficient “control” over these documents. *See Chaveriat v. Williams Pipe Line Co.*, 11 F.3d 1420, 1427 (7<sup>th</sup> Cir. 1993) (“[T]he fact that a party could obtain a document if it tried hard enough and maybe if it didn’t try hard at all does not mean that the document is in its possession, custody or control; in fact it means the opposite.”).

The burden of establishing control over the documents being sought rests with the demanding party. *See, e.g., Sparks Tune-Up Centers, Inc. v. Panchevre*, No. 90 C 4369, 1991 WL 101667, \*3 (N.D. Ill. Jun. 4, 1991). In her Order, Magistrate Judge Soat Brown noted simply Pfizer’s assertion that that the Plaintiffs “have a contractual right to obtain information about the participants and the medical benefits for which the Plaintiff funds paid.” Opinion at 7. But whether Plaintiffs have such a “contractual right” is beside the point where Plaintiffs’ ability to compel production of personal medical records is limited as a matter of law. In truth, the only evidence that Pfizer introduced in this regard was reference to the plan documents of certain funds (not even all of the 11 Plaintiffs at issue here) that permitted the “Plan Sponsor” (*i.e.*, the particular Plaintiff) to access certain protected health information for purposes of performing “Plan Administration” functions in accordance with HIPAA. *See* Pfizer’s Opposition to Plaintiffs’ Motion to Modify Discovery at 11 n.9 [Dkt. 139] (citing Southern Illinois Laborers’ & Employers Health & Welfare Fund Summary Plan Description 2005 at 53-54) (which is attached as Exhibit C hereto). But this “contractual” right of access – and Pfizer did not purport to

explain the basis of this supposed right of access for each of the 11 Plaintiffs at issue here – is limited by HIPAA. *Id.* Ex. C at 53 (incorporating HIPAA’s definitions applicable to the accessibility of protected health information). And Pfizer has not explained how, even given this supposed “right” of access to documents generally, Plaintiffs are entitled as a matter of law to disclosure of the specific *lipid profiles* of each of the plan participants.

HIPAA greatly restricts the ability of doctors to disclose the personal medical records of patients. *See* 45 C.F.R. § 164.502(a) (restricting disclosure of “protected health information” (which includes personal medical records)). Although under HIPAA third party payors such as Plaintiffs *may* be entitled to a *limited* disclosure that “summarizes the claims history, claims expenses, or type of claims experienced by individuals for whom a plan sponsor has provided health benefits under a group plan” (45 C.F.R. § 164.504(a)(1)), this exception does not include the specific *diagnoses* of the individual patients, which is precisely the information the Order would require to be produced in order to determine whether a particular Lipitor prescription was “on-label” or “off-label.” Similarly, although HIPAA permits the disclosure of such information in the absence of patient consent pursuant to a valid court order (*see* 45 C.F.R. § 164.512(e)), this provision does not render such documents under the “control” of Plaintiffs as a matter of law – it merely permits the *doctors*, who have such control, to produce the documents if a court orders *them* to do so. Further, HIPAA expressly does not preempt state law disclosure rules that are *more restrictive* than HIPAA, thus preventing Plaintiffs from obtaining personal medical records from doctors *even if* they otherwise could seek such documents in accordance with HIPAA. *See* 45 C.F.R. § 160.203(b).<sup>2</sup> At bottom, whatever “contractual rights” Plaintiffs may have notwithstanding, the simple fact is that Plaintiffs do not have “control” over the individual medical records of their plan participants sufficient to require Plaintiffs to produce these records.

**b. The Order Requires Production Of Materials That Are Outside The Scope Of Rule 26(b)(1)**

In ordering the production of information relating to the identity of specific off-label prescriptions paid for by each Plaintiff, the Order erroneously concludes that such information

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<sup>2</sup> *Cf., Northwestern Mem’l Hosp. v. Ashcroft*, 362 F.3d 923 (7<sup>th</sup> Cir. 2004) (holding that HIPAA’s disclosure requirements are *not* trumped by more-restrictive state law provision *in a suit to enforce federal law*). Indeed, in *Ashcroft*, the Court observed: “Illinois is free to enforce its more stringent medical-records privilege (there is no comparable federal privilege) in suits in state court to enforce state law”. *Id.* at 925.

remains discoverable under Rule 26. Order at 6. Under the price inflation theory pled in the SAC the identification of individual participants that received Lipitor for off-label uses is neither relevant to any claims or defenses nor is it reasonably calculated to lead to the discovery of admissible evidence.

Rule 26 does not permit unlimited discovery. Under Rule 26(b)(1), discovery is limited to the production of information “that is relevant to the claim or defense of any party . . . [or which] appears reasonably calculated to lead to the discovery of admissible evidence.”<sup>3</sup> *See also Aramark Educ. Res.*, 206 F.R.D. at 461 (“The threshold issue in any discovery dispute is determining whether the requested discovery meets the requirements of Federal Rule of Civil Procedure 26 regarding relevance”). As noted by *U.S. v. Seaga Corp.*, No. 00 C 50389, 2002 WL 31045388, at \*1 (N.D. Ill. Sept. 11, 2002), “[t]he 2000 amendments to Rule 26(b)(1) narrowed the scope of discoverable material with the inclusion of the term ‘relevant to the claim or defense of any party’ and the removal of the term ‘relevant to the subject matter involved in the pending action.’” Accordingly, where a party seeks discovery of materials that are beyond the scope of Rule 26, ordering the production of such material would be improper. *See id.* at \*2 (refusing to order production of documents that are unrelated to a party’s claim). *See also Aramark Educ. Res.*, 206 F.R.D. at 461 (noting Rule 26’s “discovery boundary”).

Here, despite completely revising the theory of damages pled in the FAC and now pleading a theory that is unrelated to whether any TPP paid for off-label prescriptions of Lipitor, the Order compels Plaintiffs to produce “information about the allegedly improper prescriptions for which Plaintiffs paid. . . .” Order at 4. The Order requires the production of information that is neither necessary nor relevant to any claims or defenses in this case. Specifically, the Order reaffirms the requirement that Plaintiffs obtain medical records release authorizations for each of their Lipitor-taking participants when the theory pled in the SAC is confined to the inflation in Lipitor’s price caused by Pfizer’s misrepresentations and omissions. But the specific cholesterol levels of patients who were prescribed Lipitor are irrelevant to the damages theory in the SAC.

Moreover, providing the information required by the Order cannot be said to be reasonably calculated to lead to admissible evidence given that the theory of damages pled in the

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<sup>3</sup> “‘Relevant evidence’ means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” Fed. R. Evid. 401.

operative complaint has no bearing on the decisions of TPPs to pay for off-label uses of Lipitor or TPPs' members use of Lipitor for off-label uses. As stated by Judge Weinstein in *In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571, 577 (E.D.N.Y. 2007), individualized proof of off-label payment are not needed in TPP suits alleging overpayment. According to Judge Weinstein "[b]ased on expert reports and available modes of economic analysis, a trier could determine that Zyprexa would have-or would not have-been sold for a reasonably precise computable lesser amount than it was sold for were it not for Lilly's alleged fraud."<sup>4</sup> See also *id.* at 578-79 ("Defendant argues that plaintiffs' use of aggregate proof, rather than individualized proof, to establish reliance is impermissible. This assertion is without merit"). The acceptable methods, which included economic modeling and aggregate proofs, cited by Judge Weinstein is the way Plaintiffs will establish damages here – evidence of individual prescriptions of Lipitor for off-label uses is completely irrelevant.

**c. Requiring Plaintiffs To Produce Evidence Of Individual Prescriptions Is Unduly Burdensome**

Production of information demanded in the Order also would provide little, if any, benefit to Pfizer. See Fed. R. Civ. P. 26(b)(2)(C)(iii). See also *Patterson v. Avery Dennison Corp.*, 281 F.3d 676, 681 (7th Cir. 2002) (Rule 26(b)(2) "empowers district courts to limit the scope of discovery if 'the discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive.'").

The ruling that "Plaintiffs have not demonstrated that it is *impossible* to produce the information about what prescriptions they paid for and which of those they consider to have been the unnecessary result of improper marketing" (Order at 7 (emphasis added)), is not the appropriate standard for evaluating the limitations on discovery under Rule 26(b)(2)(C)(iii). Rule 26's analysis turns on whether "the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues" – not whether production of the demanded discovery is theoretically possible. See Fed. R. Civ. P. 26(b)(2)(C)(iii). In requiring production

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<sup>4</sup> Even if Lipitor was properly prescribed, TPPs are still entitled to recover overpayments. See *Zyprexa*, 493 F. Supp. 2d at 578 ("While it can be assumed for purposes of this motion that the drug was properly prescribed, payers may recover the difference between the price they paid for Zyprexa and the price they would have paid for Zyprexa but for Lilly's alleged fraud.").

of individual members' use of Lipitor for off-label uses, the Order focuses only on one of the relevant factors under Rule 26(b)(2)(C)(iii) – the amount in controversy. *See* Order at 7-8. None of Rule 26(b)(2)(C)(iii)'s other factors are considered.

When taking into account the burden that responding to this discovery imposes on Plaintiffs – given that the demanded information is not relevant to the theory of damages pled in the SAC and that the information needed to establish Plaintiffs' damages is in the hands of third-parties doing business with Pfizer<sup>5</sup> – the Order imposes burdens beyond those contemplated by Rule 26. *See Berning v. UAW Local 2209*, No. 106-CV-00087, 2007 WL 1385367, at \*2 (N.D. Ind. May 4, 2007) (noting that the Seventh Circuit requires consideration of the “totality of the circumstances” when making discovery rulings) (citing *Patterson*, 281 F.3d at 681).

The burden imposed on Plaintiffs by the Order is enormous. In order to comply with the Order, Plaintiffs would be required to engage in thousands of communications with non-party plan participants in order to explain – often on an individual basis – the need for this highly sensitive information. Whether, as a technical matter, Plaintiffs have a “contractual right” (Order at 7) to access individual medical records ignores the practical difficulties of obtaining from family physicians the individual medical records of their patients, regardless of whatever right Plaintiffs may have to ask for such documents. For example, inevitably, physicians will flat-out refuse to produce individual medical records in the absence of a release signed by the patient or an Order from a local Court compelling them to turn over the documents. And when Plaintiffs seek releases from the individual patients themselves, many will be (and have been) slow in returning the forms needed to authorize release and analysis of their medical records, or will ignore them, or will have questions about the need for such highly sensitive personal health information. Having answered the participants' questions, and, presumably, received at least a reasonable number of executed authorization forms, Plaintiffs must then send those forms, with the Pfizer-approved cover letter, to the participants' Lipitor-prescribing doctors. But communicating with the doctors is not automatic, simple or administratively easy. First, a number of participants have more than one prescribing doctor. Second, for all these doctors, the Plaintiffs have to obtain addresses. The Plaintiffs and their PBMs do not typically keep such doctor-specific information.

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<sup>5</sup> *See infra* at n.5 (discussing efforts to obtain relevant documents from IMS Health).

Gathering information from individual physicians itself leads to more obstacles and red tape. Doctors often request payment before copying records, requiring further communications, correspondence, time and effort. The Plaintiffs would send funds in advance, but, not knowing the page volume of the particular participants' charts, what the particular doctor's per-page charge is, whether storage retrieval charges are involved, or numerous other variables, the Plaintiffs simply must request records and await a response. Busy doctors' offices do not often respond immediately and physicians are understandably reluctant to produce patient-specific records in the absence of a written release from the patient or an order from a local court.

And all of this time, effort and expense is so that Plaintiffs can produce information confirming their damages under their previous, now-abandoned, "increased number of prescriptions caused by off-label marketing" damages theory. The complaint under which Pfizer propounded its discovery which is the subject of the Order is no longer operative. The SAC does not require detailed patient-specific medical information to determine Plaintiffs' damages. The SAC does not allege that individual Plaintiffs were duped into paying for specific off-label prescriptions because of a fraudulent marketing campaign. Rather, the SAC alleges that Pfizer's off-label or fraudulent marketing drove demand up and increased the price of Lipitor. *See, e.g.*, SAC at ¶ 30 ("Further, Pfizer expanded the market and demand for Lipitor, creating the artificially increased prices for Lipitor, not only by illegally promoting the off-label use of the drug, but also by concealing or minimizing the health risks associated with statin use, and by wrongfully promoting Lipitor as superior to and safer than other statin alternatives.").

Plaintiffs' damage calculations will not require time consuming collections and painstaking investigations of individual medical records and prescriptions. First, Plaintiffs will continue, through discovery, to gather additional information showing that Pfizer misrepresented Lipitor's safety and efficacy in a uniform scheme of deceptive marketing that laid claim to superiority for Lipitor that did not exist or was, at best, marginal. Second, through commercially available data from Verispan and/or IMS Health, companies that compile information on patients taking Lipitor such as their LDL levels and other risk factors of heart disease, Plaintiffs will show that Pfizer's deceptive over-promoting marketing increased demand for Lipitor beyond what it would have been without the deception. Third, through expert economic testimony, Plaintiffs will show that Pfizer inflated the price of Lipitor by artificially driving demand for Lipitor. Fourth, Plaintiffs will calculate damages, through expert testimony based, among other

things, on Pfizer's own documents, publicly available prescription pricing, volume and market data, and *Daubert*-compliant econometric modeling, that determines the amount spent on Lipitor and subtracts the cost of Lipitor absent Pfizer's deceptive marketing.

Plaintiffs are not asking this Court to plow completely new ground or to invent new legal principles. Other respected courts have accepted this type of statistically-based and econometrically-modeled damages calculation in other medical and pharmaceutical litigation. See, e.g., *In re Neurontin Mktg. and Sale Practices Litig.*, 244 F.R.D. 89, 110 (D. Mass. 2007) (approving as a "widely-used statistical tool" a "time-series regression" analysis used by plaintiffs' expert to "calculate the total number of off-label prescriptions that were caused by defendants' off-label marketing activities"); *Klay v. Humana, Inc.*, 382 F.3d 1241, 1259-60 (11th Cir. 2004) (certifying class of HMO subscribers in RICO action where damage calculations can be computed "according to some formula, statistical analysis, or other easy or essentially mechanical methods"); *In re Synthroid Mktg. Litig.*, 188 F.R.D. 295, 300 (N.D. Ill. 1999) (alleging suppression of information on the efficacy of generic substitutes artificially increased demand and price: "The question of liability, therefore, will turn on whether the defendants engaged in the alleged conduct, consisting primarily of the uniform suppression of material information, not on the individual decisions and circumstances of countless people along the chain of distribution of Synthroid."); *In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571, 578-79 (E.D.N.Y. 2007) ("defendant argues that plaintiffs' use of aggregate proof, rather than individualized proof, to establish reliance is impermissible. This assertion is without merit. Statistical proof of reliance is appropriate in the RICO context where a 'sophisticated, broad-based [scheme], by [its] very nature . . . likely to be designed to distort the entire body of public knowledge rather than to individually mislead millions of people[.]' is alleged.").

The individual medical records Pfizer seeks contain the most intimate, private details of a patient's physical and mental health. Plaintiffs have no intention of using these medical records to prove their case or to calculate damages. Pfizer will not need those documents in seeking to disprove Plaintiffs' pricing claim. Nobody knows better than Pfizer how its marketing and promotional activities affect, or otherwise relate to, Lipitor's market position and pricing.<sup>6</sup>

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<sup>6</sup> As of October 5, 2007, Pfizer had not produced to Plaintiffs any IMS or Verispan data (to the extent Pfizer had located any Verispan data) that Pfizer purchased reflecting information about Lipitor sales. The parties agreed to table the issue with the understanding that Plaintiffs would first seek the information from third-parties. In order to obtain the necessary information, Plaintiffs served a subpoena dated

Indeed, to a large extent, in pleading this theory, the Plaintiffs are necessarily playing on Pfizer's home field. Given the robust statistical data on which Plaintiffs will rely, the individual patient records have, at most, limited probative value in this case.

Rule 26(c) states that a court "may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense." In *American Intern. Specialty Lines Ins. Co. v. NWI-I, Inc.*, 240 F.R.D. 401, 412 (N.D. Ill. 2007), the court held:

[A] court may limit discovery if it determines that the burden of the discovery outweighs its likely benefit. To make such a determination, the courts consider what has been dubbed the proportionality test of Rule 26(b)(2)(iii): the needs of the case, the amount in controversy, the resources of the parties, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues.

Further, "to consider the nature of the hardship and its magnitude, [courts give] more weight to interests that have a distinctively social value than to purely private interests." *Beauchem v. Rockford Prods. Corp.* No. 01 C 50134, 2002 WL 1870050, at \*2 (N.D. Ill. Aug. 13, 2002). Here, the value of individual patient data is small in comparison to the extremely intrusive nature of the discovery sought - private medical data of non-parties who happen to be members of a Fund that is alleging a damages theory unrelated to these records. Weighing the minimal to non-existent probative value of this highly sensitive personal medical information against the enormous administrative burdens of getting it, and the important privacy rights of the beneficiaries, requires reversal of the Order.

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August 24, 2007 on IMS Health. This subpoena was issued out of the District of Connecticut. A second subpoena, issued out of the Eastern District of Pennsylvania, dated October 10, 2007 was served on IMS. Particularly relevant to the Plaintiffs' claims, IMS gathers extensive data about prescription drugs, which includes, for example, the number of total prescriptions and new prescriptions, market prices of drugs, co-payments and insurance reimbursements, and the like. IMS gathers this data and, using modeling and statistics, projects national data. Pfizer buys such data from IMS, using that data, for example, to track trends in prescriptions, both new and total, determine bonuses, and measure the impact of marketing efforts. Pfizer has also purchased consulting services from IMS. IMS Health moved to quash Plaintiffs' subpoena in the Eastern District of Pennsylvania. On November 15, 2007, during a telephonic hearing on IMS Health's motion to quash before the Honorable Paul S. Diamond, the court denied IMS's motion to quash with respect to the production of documents. See Order attached hereto as Exhibit D. The information Plaintiffs expect to receive from IMS - more so than the limited information Pfizer would obtain if Plaintiffs are made to comply with the Order - is the type of information needed to establish Plaintiffs' theory under the SAC. Under these circumstances forcing compliance with the Order would be unjust. See *Berning*, 2007 WL 1385367, at \*2 (refusing to order production of information which was "obtainable from some other source that is more convenient, less burdensome, or less expensive").

**i. Beneficiary Data Has Limited Value In This Litigation**

Plaintiffs have no intention of using the medical records of its beneficiaries to prove or calculate damages. Such records are also irrelevant to rebut the statistical data cited by Plaintiffs. The number of Plaintiffs' beneficiaries is tiny in relation to the nationwide numbers of anonymous patient records on which the statistical data Plaintiffs will use to calculate damages. The individual medical records of Plaintiffs' beneficiaries would be of no value in challenging Plaintiffs' statistical analysis.

**ii. Producing Patient Data Would Be Unduly Burdensome Because It Impinges On The Privacy Of Plaintiffs' Beneficiaries**

Producing the names and the private medical records of Plaintiffs' beneficiaries is also unduly burdensome because it unnecessarily violates the privacy of third parties, who have not brought this litigation. In *Neurontin* the plaintiffs similarly agreed to prove damages solely by statistical methods. The *Neurontin* court held that it would be unduly burdensome to produce patients' medical records:

After hearing, I conclude that the burden, expense and invasion of privacy of the proposed discovery outweighs its likely benefit. See Fed. R. Civ. P. 26 (b)(2) . . . If either party intends to call a treating physician to give an opinion on effectiveness, sanitized patient records shall be produced to the extent the physician is relying on his experience with treating that patient (as opposed to a clinical trial).

*See Order, In Re Neurontin Marketing, Sales Practices*, No. 1:04-cv-10981-PBS (D. Mass. filed September 27, 2006) (Electronic Order attached hereto as Exhibit E).

Similarly, the court in *Riley v. Walgreen Co.* 233 F.R.D. 496, 501 (S.D. Tex. 2005), held that a pharmacy did not have to turn over names and prescription information of its customers in litigation brought by plaintiff alleging that his prescription was improperly filled. Plaintiff requested the name and prescription data of other patients to determine if the pharmacy made other prescription-filling errors. *Id.* The court refused to require the production of such information: "Patient prescription drug orders and medication records contain highly sensitive and personal information . . . Given the extremely sensitive information at issue, the court agrees that both redaction of names and a confidentiality agreement are appropriate." *Id.* Here, just as in *Riley*, the privacy concerns of beneficiaries far outweigh the importance of their medical

records to this litigation. None of these precedents – which were cited to the Court – are considered in the Order.

Furthermore, Plaintiffs do not keep medical records of beneficiaries in the regular course of business, and the process of obtaining medical records from doctors is unduly burdensome. *See Cohn v. Taco Bell Corp.*, No. 92 C 5852, 1993 WL 451463, at \*4 (N.D. Ill. Nov. 1, 1993) (holding plaintiff did not have to produce documents where the burden of gathering “records [was] quite large, in relation to the small value that they have in th[e] litigation”), *aff’d* 1994 WL 383975 (N.D. Ill. Jul. 20, 1994). To point out just a few of the difficulties, gleaned from the experience of the test case protocol of the Plaintiff Plumbers & Pipefitters, is highly instructive. Plumbers & Pipefitters faced an enormous burden in complying with Judge Brown’s July 19, 2007 Order<sup>7</sup> in order to produce the medical records of its beneficiaries. First, Plumbers & Pipefitters had to locate its members’ physicians’ addresses by web-based searches and other investigations. Second, in a number of cases, Plumbers & Pipefitters was unable to locate which doctor had medical records of beneficiaries. Third, many doctors who had beneficiary medical records refused to turn them over without patient consent, citing HIPAA concerns and state laws protecting patient privacy. Obtaining these medical records would likely require additional litigation. Fourth, negotiating consent with each and every beneficiary to get their medical records will surely be very time-consuming and difficult and would also likely require additional litigation if fund participants do not want their private medical records in the hands of Pfizer. Based on the experience in gathering responsive data for the Plumbers & Pipefitters, Plaintiffs abandoned the damages theory in the FAC and filed the SAC. Despite Plaintiffs’ efforts to abandon their previous theory, the Order continues to demand production of information that has very limited value to this case while imposing a monumental burden on Plaintiffs.

### CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court sustain Plaintiffs’ objections to Magistrate Judge Brown’s Order.

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<sup>7</sup> See Exhibit F attached hereto.

DATED: November 29, 2007

Respectfully submitted,

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## **EXHIBIT Q**

UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

SOUTHERN ILLINOIS LABORERS' AND  
EMPLOYERS HEALTH AND WELFARE )  
FUND; NECA-IBEW WELFARE TRUST )  
FUND; MIDWESTERN TEAMSTERS )  
HEALTH AND WELFARE FUND; THE )  
WELFARE FUND OF TEAMSTERS )  
LOCAL UNION 863; PLUMBERS & )  
PIPEFITTERS LOCAL UNION 630 )  
WELFARE TRUST FUND; CLEVELAND )  
BAKERS AND TEAMSTERS HEALTH )  
AND WELFARE FUND; ELECTRICAL )  
WORKERS BENEFIT TRUST FUND; FIRE )  
& POLICE RETIREE HEALTH CARE )  
FUND, SAN ANTONIO, LABORERS' )  
DISTRICT COUNSEL BUILDING AND )  
CONSTRUCTION HEALTH AND )  
WELFARE FUND; LABORERS' DISTRICT )  
COUNCIL HEAVY AND HIGHWAY )  
UTILITY HEALTH AND WELFARE )  
FUND, and NEW YORK CITY POLICE )  
SERGEANTS BENEVOLENT )  
ASSOCIATION HEALTH & WELFARE )  
FUNDS, individually, and on behalf of all )  
others similarly situated, )

Plaintiffs, )

v. )

PFIZER INC., )

Defendant. )

NO. 06-CV-1818

JUDGE JOHN W. DARRAH

MAGISTRATE JUDGE  
GERALDINE SOAT BROWN

**DEFENDANT PFIZER INC'S OPPOSITION TO PLAINTIFFS' AMENDED  
OBJECTIONS TO MAGISTRATE JUDGE BROWN'S ORDER DATED  
NOVEMBER 14, 2007 DENYING PLAINTIFFS' MOTION TO MODIFY DISCOVERY**

Defendant Pfizer Inc (“Pfizer”) respectfully submits this memorandum in opposition to Plaintiffs’ Amended Objections to Magistrate Judge Brown’s Order of November 14, 2007.

### **PRELIMINARY STATEMENT**

Although they charge Judge Brown with committing “violations of the Federal Rules” and ordering discovery “well outside the limits of Fed. R. Civ. P. 26(b)(1),”<sup>1</sup> blatantly mischaracterize her Order of November 14, 2007 (the “Order”), and misstate their own Complaint, Plaintiffs (or the “Funds”) do not identify any credible basis for finding that Judge Brown’s Order is anything but well reasoned and supported by both the record and the law, much less that it “is clearly erroneous or is contrary to law.” Fed. R. Civ. P. 72(a). For over eight months, Judge Brown has held numerous hearings and conferences on the parties’ discovery status and disputes and, as a result, has become exceedingly familiar with the details of this action and each of the issues addressed in the Order. Judge Brown’s Order was not the result of a knee-jerk reaction, as Plaintiffs suggest. Rather, it was issued after full briefing and oral argument on the Funds’ Motion to Modify Discovery,<sup>2</sup> which itself followed briefing and multiple hearings on the same disputed discovery requests. The Order simply directs the Funds to comply with Judge Brown’s prior rulings directing them to respond to an interrogatory served in June 2006. That interrogatory asks the Funds, who are seeking tens of billions of dollars based on alleged off-label marketing by Pfizer, to identify the allegedly improper off-label Lipitor prescriptions that they claim – in each of their successive pleadings – they have paid for.

Judge Brown certainly did not, as the Funds assert, “order[] Plaintiffs to contact hundreds of doctors across the country and . . . force them to turn over personal medical records of thousands of individual patients.” Objections at 1. Rather, Judge Brown simply ordered the Funds to identify “the allegedly improper prescriptions for which Plaintiffs paid” (Order at 4), information that she correctly determined is relevant to the Funds’ claims for “tens of billions of dollars,” and that the Funds have conceded is within their control. Indeed, the Funds were required by Rule 11 to determine whether they had support for those claims even before filing this lawsuit. Judge Brown’s findings, after an extensive record and analysis of the pleadings,

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<sup>1</sup> Pls.’ Amended Objections (“Objections”) at 5.

<sup>2</sup> As Pfizer pointed out to Judge Brown, Plaintiffs’ motion was, in fact, a motion for reconsideration, styled as a motion to modify to avoid the standard applied to motions for reconsideration.

that this information remains discoverable under the Second Amended Complaint and is not unduly burdensome for the Funds to provide, are fully supported by the Funds' own pleadings and discovery responses and entirely consistent with the Federal Rules. As they did before Judge Brown, the Funds, in their objections, ignore the express allegations in their own Second Amended Complaint in an effort to portray Judge Brown's rulings as incorrect, and offer only their counsel's conclusory claims of a burden on *counsel* to obtain and review the information. The Funds have offered no affidavits or otherwise articulated any burden on the part of the Funds.

Because Plaintiffs have not demonstrated that Judge Brown's Order is erroneous or contrary to law, this Court should overrule their objections in their entirety and affirm the Order.

### **RELEVANT FACTS AND PROCEDURAL HISTORY**

In each of their three complaints in this action, the Funds have alleged that Pfizer promoted Lipitor for cholesterol treatment in "moderate risk" patients, and that this purported "off-label" marketing caused the Funds and a putative class to pay for "unnecessary" prescriptions.<sup>3</sup> Accordingly, since discovery began in June 2006, Pfizer has requested that the Funds identify the allegedly improper off-label Lipitor prescriptions for which they claim to have paid. *See* Pfizer's Mem. in Support of Motion to Compel [D.E. 78] at 11-12. Because the Funds claim billions in damages and have contractual rights to obtain their members' prescription and medical records,<sup>4</sup> Pfizer reasonably expected that they had identified the allegedly improper prescriptions for which they were claiming damages as part of their good faith pre-filing investigation. However, over ten months after Pfizer first requested the information in June 2006, and after entry of a comprehensive protective order, the Funds had not identified a single allegedly off-label prescription and refused to provide the information. Pfizer moved to compel [D.E. 78], and the motion was assigned to Judge Brown.

Following a hearing on June 13, 2007, Judge Brown ordered Plaintiffs to start with one Fund and identify each allegedly improper off-label Lipitor prescription for which that Fund paid. *See* 6/13/07 Transcript [D.E. 95] ("Tr.") at 36-39 ; 6/13/07 Minute Order [D.E. 92]. Judge Brown noted that the prescription information is relevant to Pfizer's defense for two reasons:

<sup>3</sup> *See, e.g.*, Compl. ¶¶ 2-3, 5-7, 49, 51; Am. Compl. ¶¶ 2-3, 5-16, 64, 65; Second Am. Compl. ¶¶ 3-5, 8-18, 80, 108-77, 220, 241.

<sup>4</sup> As Judge Brown noted in her Order, the Funds do not dispute that they have a contractual right with their members to obtain the members' medical records and information. *See* Order at 7.

“One, [to] identify the damages; two, [to] dispute, on a particularized basis, whether or not the prescription was improper.” Tr. at 28. Judge Brown further explained:

THE COURT: The matter that the defendant is seeking is clearly discoverable. There’s just no question about it. And *the defendant is not required to subscribe to your theory of your estimation of damages.* The defendant – Just sitting here I can say I can foresee an argument that although in theory there might be some over-marketing of Pfizer’s Lipitor that was based on this projected marketing plan, there would be a question about either whether or to what degree any damages were incurred by these individual plaintiffs for such activity.

You’ve got to prove, as plaintiffs, not only that there was overly-aggressive marketing but actually that you were damaged by it and you were damaged by it in some way that is more than just speculation. And to the extent that the defendant is seeking to explore that, whether by your theory or to refute it by taking discovery to prove that your theory has no factual basis if you go on a more modeled, as you say, manner, that’s still within the scope of discovery.

Now there are a lot of known knowns here, or at least known to the funds. The funds know every participant. They know that. It’s a large group of people but they know it. It’s a known known, as Donald Rumsfeld would say.

They also know or can find out those participants who received benefits for prescriptions. That’s a known known. They can then narrow it down to those who received prescriptions for Lipitor. Now it gets a little more complicated when you try to narrow it down to off-label because, as I discussed earlier, my understanding is that off-label is a phrase that needs some definition and further complicated by the fact that not every, quote, “off-label,” the parties, concede, usage of a particular drug is necessarily an improper usage of that particular drug and it’s really only improper usages that I understand the plaintiffs are seeking any remedy for.

So, you know, there’s a lot there but there’s a lot of potential there. I certainly think that this is an answer that can be made and certainly one that is going to be, I foresee, really a substantial part of any discussion about damages. *Whether or not the plaintiff thinks that this is the way they want to prove them or not, it’s going to be a part of the discussion of damages because the defendant is going to approach it perhaps in that way. So it is certainly discoverable.*

Tr. at 32-33 (emphasis added).

Judge Brown further determined that the Funds’ claim that *they* may attempt to use an undisclosed statistical model, rather than individual prescription information, to ultimately establish damages, did not insulate them from responding to Pfizer’s requests:

THE COURT: We’ve got to have facts. You’ve got to have facts, and the underlying fact is that the plaintiff is claiming billions of dollars were paid unnecessarily by the funds for improper Lipitor prescriptions. So you’ve got to

break out in some way what prescriptions you believe were improper. Actual prescriptions, not theoretical prescriptions for some theoretically-modeled universe. But actual prescriptions that you believe were improperly prescribed for which your clients improperly paid.

The defendants have a right to get some concrete on this. This is not – This isn't abstraction. This isn't speculation. This is concrete claimed damages. We're going to have some concrete information to refute it or support it, whatever it does. But we'll find a way to get at what specificity. And you know, I'm hearing you that it's a big task, but I think you might – You've got to find some ways that you think you can approach it because I'm going to compel it and that's going to be the bottom line. You find a reasonable way to do it.

... I think the question is one that, though difficult of answer, is not unduly burdensome in light of what the claimed damages are here, the nature of the claim. The only reason it becomes difficult is because there are so many plaintiffs with so many people.

Tr. at 36-37. On August 28, 2007, after the first Fund, Plumbers & Pipefitters, responded to Pfizer's interrogatory by providing information about just six Fund members, Judge Brown granted Pfizer's motion to compel the other Funds to respond to Pfizer's interrogatory and identify the allegedly improper off-label Lipitor prescriptions for which they claim to have paid. 8/28/07 Minute Order [D.E. 115].

In an admitted attempt to avoid the discovery directed by Judge Brown, the Funds immediately amended their complaint and claimed that they had changed direction to a modified "price inflation" theory of damages, that is, that Pfizer's alleged improper marketing of Lipitor created an "artificially inflated" price for the medicine. Objections at 3. The Funds' Second Amended Complaint ("SAC"), however, is substantially similar to, and includes all of the primary allegations found in, the First Amended Complaint ("FAC"), including the Funds' claims that Pfizer promoted Lipitor for off-label purposes and that Plaintiffs paid for improper or "unnecessary" off-label Lipitor prescriptions. *See, e.g.*, SAC ¶¶ 4, 5, 8-18, 70, 73, 80, 108-77, 220, 227, 241, 260, 270, 274, 283, 290, 295, 301, 305. In fact, 162 paragraphs in the SAC are identical to those in the FAC, and seventeen others are the same, but for stylistic edits.<sup>5</sup> Indeed, in their briefing in support of their motion for leave to amend, the Funds represented to this

<sup>5</sup> The Funds also expanded the scope of the case, and discovery, by adding forty-seven new paragraphs, primarily asserting that Pfizer failed to disclose health risks about Lipitor and made inaccurate superiority claims.

Court that they would comply with Judge Brown's orders and that Pfizer would "surely suffer no undue prejudice" because the Funds' discovery obligations would be unchanged. Pls.' Reply Mem. in Support of Mot. for Leave to File SAC [D.E. 123] at 5

After filing the SAC, Plaintiffs moved to "modify" Judge Brown's Order of August 28, 2007, asserting that the prescription information was not relevant under the SAC and would be unduly burdensome for the Funds to provide. [D.E. 131] Pfizer opposed Plaintiffs' Motion to Modify [D.E. 139], the Funds filed a reply under seal [D.E. 143], and Judge Brown heard argument on September 26, 2007, before taking the matter under advisement. [D.E. 144] *See* 9/26/07 Transcript, attached hereto as Ex. A.

In her Order of November 14, 2007, denying Plaintiffs' Motion to Modify and directing the Funds to comply with her Order of August 28, 2007, and identify the allegedly off-label prescriptions for which they claim they have paid,<sup>6</sup> Judge Brown did not, as the Funds assert in their Objections, instruct the Funds on how they should obtain the prescription information. This is simply a fabrication by Plaintiffs. The Order notes that the Funds themselves had indicated, "[a]s late as September 5, 2007," that "they planned to identify the prescriptions that were the result of improper marketing by identifying each participant who received prescriptions for Lipitor, and by reviewing the participant's medical records, to determine if the Lipitor prescription was for off-label uses." Order at 6 (citing Ex. A to D.E. 143, at Request No. 13).

### **ARGUMENT**

#### **I. RULE 72(A) REQUIRES PLAINTIFFS TO ESTABLISH THAT JUDGE BROWN'S ORDER IS CLEARLY ERRONEOUS OR CONTRARY TO LAW**

"The Federal Rules of Civil Procedure grant magistrate judges broad discretion in resolving discovery disputes." *Ocean Atl. Woodland Corp. v. DRH Cambridge Homes, Inc.*, No. 02 C 2523, 2004 U.S. Dist. LEXIS 4698, at \*9 (N.D. Ill. Mar. 22, 2004). A district court may modify or reverse a magistrate judge's discovery order only if it finds the ruling to be "clearly erroneous or . . . contrary to law." Fed. R. Civ. P. 72(a); *see also* 28 U.S.C. 636(b)(1)(A). Although the Funds attempt to create confusion about the appropriate standard of review of Judge Brown's Order under Rule 72(a), the law in this Circuit is very clear: "The district court

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<sup>6</sup> This Court granted the parties' joint motion for a stay of the December 21, 2007, deadline for compliance with the Order, until ten days after this Court rules on the Funds' Objections. [D.E. 180]

must review the magistrate judge's ruling under the 'clear error standard,' which 'means that the district court can overturn the magistrate judge's ruling only if the district court is left with the definite and firm conviction that a mistake has been made.'" *FTC v. Pac. First Benefit, LLC*, 361 F. Supp. 2d 751, 754 (N.D. Ill. 2005) (quoting *Weeks v. Samsung Heavy Indus. Co.*, 126 F.3d 926, 943 (7th Cir. 1997)) (affirming order of Judge Brown directing defendant to respond to discovery); see also *Rubin v. Islamic Republic of Iran*, No. 03 CV 9370, 2007 U.S. Dist. LEXIS 54983, at \*7 (N.D. Ill. July 26, 2007) ("Review is deferential, and a magistrate judge's ruling will be set aside or modified only if the ruling is clearly mistaken."); accord *Hutchinson v. Blagojevich*, No. 04 C 2947, 2006 U.S. Dist. LEXIS 36071, at \*6-7 (N.D. Ill. Apr. 12, 2006).

As these authorities confirm, Rule 72(a)

sets the hurdle high. See 12 Charles A. Wright, Arthur Miller, & Richard L. Marcus, *Federal Practice and Procedure* § 3069, at 350-51 (2d ed. 1997) ("it is extremely difficult to justify alteration of the magistrate judge's nondispositive actions by the district judge."). The Seventh Circuit put it more vividly by characterizing a decision as clearly erroneous only if it strikes the court as "wrong with the force of a five-week-old, unrefrigerated, dead fish." *Parts & Elec. Motors, Inc. v. Sterling Elec., Inc.*, 866 F.2d 228, 233 (7th Cir. 1988).

*Finwall v. City of Chicago*, 239 F.R.D. 504, 506 (N.D. Ill. 2006); see also *Am. Hardware Mfrs. Assoc. v. Reed Elsevier Inc.*, No. 03 C 9421, 2007 U.S. Dist. LEXIS 35352, at \*5, \*5-10 (N.D. Ill. May 11, 2007) (noting that objectors "face a high burden in their attempt to show that [a magistrate judge's] ruling was in error"; affirming, over relevance objections, magistrate judge's order directing parties to produce financial and employment documents). In *Jackson v. City of Chicago*, for example, Judge Filip rejected, under the clear error standard, plaintiff's objections to an order by Judge Brown directing plaintiff, *inter alia*, to supplement her interrogatory responses. See No. 03 C 8289, 2006 U.S. Dist. LEXIS 56675, at \*13, \*28-37 (N.D. Ill. July 31, 2006). Finding Judge Brown's "directive . . . not outside the mainstream at all" (*id.* at \*34), the court concluded:

[T]he Court finds it inappropriate to second-guess Magistrate Judge Brown's discovery order given that she was best-positioned – after patiently conducting a painstaking response-by-response review of Plaintiff's interrogatory responses in open court – to determine what level of detail was necessary to ensure that Plaintiff provided fair and appropriate responses to the relevant interrogatories posed.

*Id.* at \*35-36; accord *Smith v. Sprint Commc'ns Co. L.P.*, No. 99 C 3844, 2003 U.S. Dist. LEXIS

2803, at \*6, \*9 (N.D. Ill. Feb. 26, 2003) (denying objections to discovery ruling by Judge Brown under clear error standard, finding “Magistrate Judge Brown’s ruling to be in complete accord with the [relevant] Seventh Circuit precedent”).

As established below, Plaintiffs have not identified any error in Judge Brown’s decision that would justify disturbing her Order under Rule 72(a)’s deferential standard.<sup>7</sup>

## II. JUDGE BROWN’S FINDING THAT THE INFORMATION IS DISCOVERABLE IS NEITHER CLEARLY ERRONEOUS NOR CONTRARY TO LAW

As Judge Brown recognized, Rule 26 provides that a party “may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party.” Order at 4 (citing Fed. R. Civ. P. 26(b)(1)). Where a request appears relevant, the objecting party bears the burden of showing why its objection or failure to respond is proper. *See Meyer v. S. Pac. Lines*, 199 F.R.D. 610, 612 (N.D. Ill. 2001). Judge Brown’s finding that information about the allegedly unnecessary Lipitor prescriptions for which the Funds claim to have paid remains relevant and subject to discovery is fully supported by the Funds’ SAC and Rule 26. In the SAC, as in their original Complaint and the FAC, the Funds allege that Pfizer promoted Lipitor for off-label purposes and that Plaintiffs paid for improper off-label Lipitor prescriptions. *See, e.g.*, SAC ¶¶ 4, 5, 8-18, 70, 73, 80, 108-77, 220, 227, 241, 260, 270, 274, 283, 290, 295, 301, 305; *see also* Order at 5 (“[T]he Second Amended Complaint continues the allegations that Plaintiffs paid for improper prescriptions.”). Indeed, as Judge Brown noted (Order at 5), in their brief in support of their motion for leave to file the SAC, the Funds defined “Plaintiffs” as “third-party payors who paid for an increased number of prescriptions for Lipitor resulting from Pfizer’s illegal marketing practices.” Pls.’ Mem. Supp. Mot. Leave File Second Am. Compl.

<sup>7</sup> Neither of the cases cited by Plaintiffs in which the district court decided to modify a magistrate judge’s order (*see* Objections at 5-6) support such an outcome here. In *National Union Fire Insurance Co. of Pittsburgh v. Continental Illinois Corp.*, the court rejected plaintiff insurers’ relevance and undue burden objections to the magistrate judge’s order directing them to produce communications with reinsurers, and modified the order only to require that plaintiffs first provide indices of documents produced in six other lawsuits, rather than all of the documents themselves. 116 F.R.D. 78, 82-86 (N.D. Ill. 1987). In *Doe v. Aramark Educational Resources, Inc.*, a Tennessee court reversed the magistrate judge’s order directing defendant to produce settlement agreements between it and plaintiffs in several related cases because plaintiffs intended to use the agreements to establish liability, in direct contravention of Rule 408 of the Federal Rules of Evidence. 206 F.R.D. 459, 463-64 (M.D. Tenn. 2002). The Funds do not identify any similar improper purpose behind Pfizer’s request for the prescription information at issue here.

[D.E. 113-3] at 2 (emphasis added). The Funds thus plainly have not, as they asserted before Judge Brown and now assert before this Court, “abandoned” their theory of ““increased number of prescriptions caused by off-label marketing.”” Objections at 11. As such, Judge Brown properly rejected the Funds’ patent mischaracterization of the SAC and held:

Contrary to Plaintiffs’ assertions . . . the Second Amended Complaint does, in fact, allege that a primary component of Pfizer’s allegedly illegal scheme has been an effort to expand the market for Lipitor by promoting the off-label use of the drug, which “resulted in an artificially increased number of Lipitor prescriptions *for which the Plaintiff Funds were required to pay . . .*” (Second Am. Compl. ¶¶ 3-4, emphasis added.) Plaintiffs further claim that, “Plaintiffs paid improperly inflated prices for Lipitor and *for an increased number of Lipitor prescriptions* generated through Pfizer’s illegal marketing tactics.” (*Id.* ¶ 5, emphasis added.)

Each of the Plaintiffs alleges not only that it paid an inflated price for Lipitor but also that it paid for “an increased number of Lipitor prescriptions generated through Pfizer’s illegal marketing campaign.” (*Id.* ¶¶ 8-18.)

*Thus, the claim that Plaintiffs were injured because they paid for unwarranted Lipitor prescriptions did not disappear with the filing of the Second Amended Complaint. Plaintiffs continue to allege that Pfizer’s alleged scheme caused Lipitor to be prescribed to persons for whom the drug is not medically necessary or indicated for use, costing the third-party payors “billions of dollars.”* (*Id.* ¶ 110.)

Order at 5 (final emphasis added).

In their Objections, the Funds do not even acknowledge, much less identify a clear error in, Judge Brown’s analysis of their SAC or her conclusion that “the allegations of the Second Amended Complaint contain substantially the same claims that Plaintiffs paid for an unnecessarily and artificially increased number of prescriptions.” Order at 6-7. Nor do they attempt to reconcile – because they cannot – their contention that “whether a particular Lipitor prescription was written for on-label or off-label use is now completely irrelevant” (Objections at 2),<sup>8</sup> with any of the allegations cited by Judge Brown. Rather, the Funds merely repeat their argument that because they have re-cast their theory of how they believe *damages* can be calculated in this case, Pfizer should be limited to: (i) conducting discovery only on the allegedly “inflated price” the Funds claim they have paid for Lipitor; and (ii) obtaining discovery

<sup>8</sup> Of course, the Funds later characterize such information as having “minimal relevance” (Objections at 5), “limited probative value” (*id.* at 13), and “very limited value.” *Id.* at 15.

information from three sources, none of which is the Funds themselves. *See, e.g., id.* (“the relevant inquiry is the inflated price”; “this theory of damages can be proved (and defended by Pfizer) entirely based on publicly available data, data obtained from third party market-survey companies (such as Verispan and IMS Health), and from information within Pfizer’s possession”); *see also id.* at 12 (“Plaintiffs have no intention of using these medical records to prove their case or to calculate damages. Pfizer will not need those documents in seeking to disprove Plaintiffs’ pricing claim.”).

Judge Brown correctly rejected the Funds’ argument that their modified damages theory should define Pfizer’s discovery rights:

Although Plaintiffs’ damage calculation is now based on a theory that Plaintiffs had to pay an artificially inflated price for Lipitor prescriptions ([SAC] ¶¶ 6, 178), *the underlying premise is that the price inflation was the result of fraudulently increased demand. (Id. ¶ 5.) The cause of Plaintiffs’ injuries is alleged to have been that Plaintiffs incurred additional costs resulting from paying for the increased number of Lipitor prescriptions, as well as paying for Lipitor at an artificially inflated price. (Id. ¶ 220.)*

Order at 5-6 (emphasis added). Pfizer is certainly entitled, as Judge Brown found, to obtain discovery that is relevant to this “underlying premise” of liability and damages, that is, that Pfizer’s marketing caused the Funds and others to pay for unnecessary off-label Lipitor prescriptions: “Pfizer has a right to discover the information that would confirm or refute those allegations, whether or not Plaintiffs are interested in using that information in their own case.” Order at 7; *see also* 6/13/07 Tr. [D.E. 95] at 32-33, 36-37; *In re ATM Fee Antitrust Litig.*, No. C 04-02676, 2007 U.S. Dist. LEXIS 47943, at \*14 (N.D. Cal. June 25, 2007) (noting that the scope of discovery is defined by “the specific subject matter presented by Plaintiffs’ complaint” and “is not limited to [one party’s] theory of the case”). For example, to defend against the Funds’ claims that they have paid for “unnecessary” off-label Lipitor prescriptions as a result of Pfizer’s promotion, Pfizer must be permitted to explore whether the Funds actually paid for any Lipitor prescriptions that fall within the Funds’ definition of “off-label” and test whether any such prescription was written by a doctor based on his or her independent judgment, training, and patient assessment, or whether it was written based on some allegedly improper promotion or

advertisement by Pfizer.<sup>9</sup> Indeed, notwithstanding their claims that the prescription information that Judge Brown has directed them to provide is no longer relevant, the Funds themselves are aggressively seeking prescription information, to the extent it exists, from Pfizer and from a non-party provider of prescription data and analysis, IMS Health. *See* Objections at 12-13 & n.6.

Moreover, as Pfizer has submitted in its Motion to Dismiss the SAC, Plaintiffs' fraud-on-the-market or price inflation theory of causation and damages has been expressly rejected by numerous federal and state courts outside of the securities fraud context. It should not, therefore, circumscribe Pfizer's discovery. Indeed, courts have held that cases involving prescription drug marketing are particularly ill-suited for the kind of market or statistical theories the Funds seek to apply here. *See Prohias v. Pfizer, Inc.*, 485 F. Supp. 2d 1329, 1337 (S.D. Fla. 2007) (rejecting "plaintiffs' claim that they have been injured by 'price inflation' [as a result of Pfizer's marketing of Lipitor] because, in the context of the pharmaceutical market, such damages are purely speculative"); *accord In re Rezulin Prods. Liab. Litig.*, No. 00 Civ. 2843, 2007 WL 4165703, at \*2-3 (S.D.N.Y. Nov. 26, 2007); *Heindel v. Pfizer Inc.*, 381 F. Supp. 2d 364, 369, 380 (D.N.J. 2004).<sup>10</sup>

But even if there were merit to Plaintiffs' price inflation theory, Pfizer would still be entitled to the prescription information that is the subject of the Order because, as established above and set forth in the Order, it remains directly relevant to Plaintiffs' theories of liability and causation. Contrary to the Funds' contention, the fact that a few courts may have "accepted . . . statistically-based and econometrically-modeled damages calculation in other medical and pharmaceutical litigation" (Objections at 12), does not support the Funds' position that Pfizer should be precluded from obtaining discovery on anything other than Plaintiffs' theory of damages. In *In re Zyprexa*, for example, in which the court denied both sides' motions for summary judgment, Judge Weinstein did not conclude, as the Funds assert that he did, that

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<sup>9</sup> Notwithstanding the Funds' repeated references to a statistical model for establishing damages on an aggregate basis, what is before this Court are claims by eleven individual Plaintiffs, each of whom must independently prove its own claims and respond to Pfizer's discovery. *See, e.g., Palmer v. City of Chicago*, 755 F.2d 560, 570 (7th Cir. 1985) ("[N]amed plaintiffs who represent a class 'must allege and show that they personally have been injured . . .'" (citation omitted)).

<sup>10</sup> *See also Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 177-78 (D.D.C. 2003); *Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co.*, 929 A.2d 1076, 1088 (N.J. 2007); *N.J. Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 178-79 (N.J. Super. Ct. App. Div. 2003).

“individualized proof of off-label payment are not needed in TPP suits alleging overpayment.” Objections at 9. *See In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571, 579 (E.D.N.Y. 2007). Indeed, although the court ruled that plaintiffs may *try* to employ a theory of aggregate proof, it emphasized that it was “not clear that plaintiffs can prove any damages, whether they attempt to prove overpayment *on a case-by-case basis* . . . or through statistical analysis.” *Id.* at 576 (emphasis added).<sup>11</sup> Judge Weinstein did not make any ruling on discovery, much less foreclose discovery of individual prescription information – as the Funds seek to do here – merely because plaintiffs asserted a prescription medicine “overpricing claim.” *Id.*

In sum, it is the Funds’ assertion that “[t]he Order requires the production of information that is neither necessary nor relevant to any claims or defenses in this case” (Objections at 8) – and not Judge Brown’s ruling – that is clearly erroneous. As Judge Brown recognized:

In light of the allegations of the Second Amended Complaint, the scope of discovery plainly includes not only the total number of Lipitor prescriptions for which each Plaintiff fund paid as well as the amount paid for those, but also the identity of the prescriptions that Plaintiffs claim were the “increased” prescriptions for which each Plaintiff fund paid that were caused by Pfizer’s alleged marketing scheme.

*Id.* at 6. Accordingly, this Court should overrule the Funds’ relevance objections.

### **III. JUDGE BROWN’S FINDING THAT THE DISCOVERY IS NOT UNDULY BURDENSOME IS NEITHER CLEARLY ERRONEOUS NOR CONTRARY TO LAW**

Judge Brown was correct both in determining that the Funds have control over information about the allegedly improper prescriptions for which they claim to have paid and in rejecting their argument that it would be unduly burdensome to provide the information. Plaintiffs’ Objections, which rely on misstatements of both fact and law, should be overruled.

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<sup>11</sup> Similarly, in *In re Neurontin*, on which the Funds rely, Judge Saris *denied* plaintiffs’ motion to certify classes of consumers and third-party payors seeking to recover for purchases of Neurontin for off-label purposes. *In re Neurontin Mktg. and Sale Practices Litig.*, 244 F.R.D. 89, 115 (D. Mass. 2007). Although the denial was without prejudice, the court identified a number of problems with plaintiffs’ proposed aggregate statistical approach, including the inability to identify “which doctors prescribed Neurontin based on [defendant’s] promotion as opposed to lawful off-label prescribing by a doctor who is exercising his own medical judgment.” *Id.* at 113; *see also id.* at 114-15 (finding statistical approach “problematic” with respect to third-party payor claims since it was not clear that they could “distinguish between payments for on- and off-label prescriptions”).

**A. The Information Is Under the Funds' Control**

"[I]t is well-settled that a party need not have actual possession of [discoverable information] to be deemed in control of [it]; rather, the test is whether the party has a legal right to obtain [it]." *Dexia Credit Local v. Rogan*, 231 F.R.D. 538, 542 (N.D. Ill. 2004); (internal quotation marks and citation omitted); *accord Engel v. Town of Roseland*, 3:06 CV 430, 2007 U.S. Dist. LEXIS 73645, at \*10-11 (N.D. Ind. Oct. 1, 2007) ("A party can have a legal right to obtain documents from another person or entity that the party does not otherwise control."; "control" includes "a contractual right to obtain"). As Judge Brown found, the Funds did not dispute Pfizer's assertion, based on the Funds' own discovery responses, that the Funds "have a contractual right to obtain information about the participants and the medical benefits for which the Plaintiff funds paid." Order at 7. Although the Funds attempt, in their Objections, to obscure their concession of a legal right to obtain the information necessary to comply with the Order, they do not dispute it.<sup>12</sup> Moreover, the Funds' argument that "whether [they] have such a 'contractual right' is beside the point where [their] ability to compel production of personal medical records is limited as a matter of law" (Objections at 6), is meritless because the Funds misconstrue federal law governing disclosure of protected health information.

It is well established that parties are entitled to obtain relevant non-party medical records and other protected health information during discovery where, as here, Plaintiffs have put the medical information at issue and the court has entered a HIPAA-compliant protective order.<sup>13</sup> *See, e.g., United States ex rel. Camillo v. Ancilla Sys., Inc.*, 233 F.R.D. 520, 522 (S.D. Ill. 2005) ("HIPAA permits protected health information to be revealed in response to a discovery request, if the parties . . . have asked the Court for a protective order."); *accord Ligas v. Maram*, No. 05 C 4331, 2007 U.S. Dist. LEXIS 58911, at \*19 (N.D. Ill. Aug. 10, 2007); *State Farm Mut. Auto. Ins.*

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<sup>12</sup> Indeed, the letter the Funds sent to doctors in connection with its collection of medical records for the "test" Fund, Plumbers & Pipefitters, advised doctors that: "our members have authorized us, in our plan documents, to obtain such . . . information when the Fund is making a claim based on benefits the Fund paid on behalf of its members;" "HIPAA permits disclosure of protected health information in a judicial proceeding"; and "all protected health information exchanged between the parties in the case is subject to a HIPAA-authorized Confidentiality Agreement." [Ex. A to D.E. 106]

<sup>13</sup> As Pfizer pointed out in its opposition to Plaintiffs' Motion to Modify, and Plaintiffs do not dispute, the protective order in place in this litigation was reviewed and commented on, before it was entered, both by the Funds' counsel and several of the Funds' HIPAA experts for the specific purpose of insuring that participant information would be protected. Opp. to Mot. to Modify [D.E. 139] at 11-12.

*Co. v. Accurate Med., P.C.*, CV 2007-0051, 2007 U.S. Dist. LEXIS 34410, at \*2-4 (E.D.N.Y. May 10, 2007). Furthermore, contrary to the Funds' argument that they would be unable to obtain medical records and information in states with disclosure rules that are more restrictive than HIPAA (Objections at 7), the Seventh Circuit and other courts have expressly held that "in a federal question suit," such as the instant federal RICO action (*see* SAC ¶ 22), "state privacy and privilege laws do not apply, regardless of whether the state law might be more restrictive than the applicable federal rule." *Ligas*, 2007 U.S. Dist. LEXIS 58911, at \*20 (citing *Northwestern Mem. Hosp. v. Ashcroft*, 362 F.3d 923, 925 (7th Cir. 2004)); *accord Camillo*, 233 F.R.D. at 522-23 ("The Court of appeals for the Seventh Circuit ruled in *Northwestern Memorial Hospital v. Ashcroft* that a more restrictive state law cannot be used in a federal-question action . . . to hamstring the enforcement of federal law."); *Accurate Med.*, 2007 U.S. Dist. LEXIS 34410, at \*2-3.<sup>14</sup> The Seventh Circuit's decision in *Northwestern Memorial* plainly supports Pfizer's, not the Funds', position, since this is not a "suit[] in state court to enforce state law," but a federal question suit in federal court. Objections at 7 n.2 (quoting *Northwestern Mem. Hosp.*, 362 F. 3d at 925). Judge Brown cited the Seventh Circuit's holding at the hearing on the Funds' Motion and admonished Plaintiffs' counsel to "take great care in citing Judge Kocoras's decision," which the Seventh Circuit reversed on this issue. 9/26/07 Tr. (Ex. A hereto) at 17-19.<sup>15</sup>

Accordingly, the Funds have not identified any mistake in Judge Brown's finding that the Funds have control over the information necessary to identify any allegedly off-label Lipitor prescriptions for which they have paid. The Funds have both an undisputed contractual right to obtain their members' medical information and the legal right to seek such information pursuant to the parties' agreed HIPAA-compliant protective order, which preempts state law requirements.

<sup>14</sup> The Funds did not raise any state law issues during the parties' negotiation of the protective order and have not challenged Pfizer's discovery requests under any specific state law provisions. Moreover, the Funds agreed to a form letter to physicians that would enclose an authorization executed by the Fund member for whom medical information is sought.

<sup>15</sup> The Funds' reliance on *Riley v. Walgreen Co.*, 233 F.R.D. 496 (S.D. Tex. 2005) (Objections at 14) is misplaced. The court in that state law diversity action applied Texas's law governing the disclosure of patient information, rather than HIPAA, which controls here, in granting Walgreen's requests to provide the requested prescription records with patient names redacted and pursuant to a confidentiality order, like that already in effect here. 233 F.R.D. at 501.

## B. The Order Does Not Impose An Undue Burden

Judge Brown's finding that it would not be unduly burdensome for the Funds to obtain – pursuant to their contracts with their members – “the medical information required to determine which of the Lipitor prescriptions were ‘unnecessary’ or ‘unwarranted’,” is similarly free of error. Order at 6. Rule 26 allows the court to consider whether “the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties’ resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.” Fed. R. Civ. P. 26(b)(2)(C)(iii). The Funds erroneously assert that “the Order focuses only on one of the relevant factors . . . – the amount in controversy.” Objections at 10. Judge Brown plainly considered the importance of the issues at stake and of the proposed discovery to resolving those issues:

Given the large sums of money that Plaintiffs seek, it is understandable that Pfizer wants to know whether Plaintiffs’ own experiences support their claims. Particularly striking is the fact that the fund selected by the Plaintiffs to provide the first answer to Pfizer’s interrogatory identified at most 6 *individuals*. As this court expressed at the hearing on August 28, 2007, the parties’ judgments about how to proceed, including, for example, whether settlement is possible, depend on getting a firm grasp of the facts behind the allegations.

Order at 8. Judge Brown also considered the Funds’ ability to obtain the prescription information, noting that they had “not dispute[d]” Pfizer’s assertion that they have a contractual right to obtain it, and “had a plan as to how to obtain [it] in September 2007.” *Id.* at 7-8.

The Funds do not address these findings, other than to assert through the unsworn, conclusory statements of their attorneys in a brief, that “[t]he burden imposed on Plaintiffs by the Order is enormous.” Objections at 10. This is insufficient to establish undue burden under the Rules. See *In re Sulfuric Acid Antitrust Litig.*, 231 F.R.D. 351, 360-61 (N.D. Ill. 2005) (“In order to demonstrate undue burden, the plaintiffs must provide affirmative proof in the form of affidavits or record evidence. . . . [T]he ipse dixit of counsel . . . is not sufficient.”). The Funds have not offered a single affidavit from any Fund or otherwise articulated any burden on the part of the Funds. The bases for Plaintiffs’ burden objection – that they have to search for doctors’ addresses, make some telephone calls, review medical records to identify alleged off-label prescriptions, and correspond with doctors to obtain records (Objections at 10-11) – all relate to tasks that the Funds’ attorneys, legal assistants, or retained healthcare professional will perform. The fact that the Funds’ counsel may have to find some addresses, or send out letters, or review

some documents, is not the kind of “undue burden” that is sufficient to deny Pfizer its right to conduct discovery in a case where the Funds are seeking billions of dollars.<sup>16</sup> These are simply routine aspects of the litigation process that the Funds, not Pfizer, voluntarily initiated.

The lone example of “burden” that the Funds describe – the “experience of the test case protocol of the Plaintiff Plumbers & Pipefitters” (Objections at 15) – is illusory, or at best, greatly exaggerated. The Funds describe a few complications that obviously resulted from their own failure to follow the basic protocol of medical records collection in a post-HIPAA world by providing patient authorizations. Nonetheless, even without an authorization and an agreed form letter, Plaintiffs were able to perform the task within a few weeks. As noted, the parties subsequently worked out and presented to Judge Brown an agreed letter to physicians that would accompany valid authorizations from Fund participants, thus greatly facilitating the records retrieval process.

Finally, the Funds disingenuously contend that it “would be unjust” to enforce the Order because IMS is purportedly a more convenient source of the prescription information *the Funds* are seeking. Objections at 12-13 n.6. Of course, the Funds do not, and cannot, credibly equate the data they are seeking from IMS to information about the Lipitor prescriptions for which they have actually paid. But more importantly, as Judge Brown determined, Pfizer is plainly not restricted to the discovery that the Funds believe they need to establish their claims.

### CONCLUSION

For the foregoing reasons, Pfizer respectfully requests that the Court overrule Plaintiffs’ Amended Objections in their entirety and affirm Judge Brown’s Order of November 14, 2007.  
DATED: December 17, 2007

/s/Andrew J. Jarzyna

Edward M. Crane

R. Ryan Stoll

<sup>16</sup> The Funds’ burden cases are inapposite. In *Cohn v. Taco Bell Corp.*, No. 92 C 5852, 1993 WL 451463 (N.D. Ill. Nov. 1, 1993), the court found that the documents in question were “almost completely irrelevant” and a connection with the lawsuit “manifestly missing.” *Id.* at \*4. In contrast, as Judge Brown held, the off-label prescription information that Pfizer seeks is directly relevant to the Funds’ claims that they have paid for unnecessary off-label prescriptions. In *Berning v. UAW Local 2209*, No. 1:06-CV-00087, 2007 WL 1385367, at \*3 (N.D. Ind. May 4, 2007), the court quashed plaintiff’s subpoena to depose the administrative judge who had heard plaintiff’s worker’s compensation dispute both because plaintiff could obtain the administrative record and because there is a general bar against “probing the mental processes in [a judge’s] deliberations.”

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**CERTIFICATE OF SERVICE**

I, Andrew J. Jarzyna, an attorney, certify that on this 17th day of December, 2007, one true and correct copy of the foregoing OPPOSITION TO PLAINTIFFS' AMENDED OBJECTIONS TO MAGISTRATE JUDGE BROWN'S ORDER DATED NOVEMBER 14, 2007 DENYING PLAINTIFFS' MOTION TO MODIFY DISCOVERY was served through this Court's electronic filing system upon the following counsel for Plaintiffs: George S. Bellas, gsb@cliffordlaw.com; Robert A. Clifford, rac@cliffordlaw.com; Sidney S. Liebesman, sliebesman@gelaw.com; Patrick J. O'Hara, patrick@cavanagh-ohara.com; and Thomas K Prindable, tkp@cliffordlaw.com.

/s/Andrew J. Jarzyna  
Andrew J. Jarzyna

# **EXHIBIT R**

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

SOUTHERN ILLINOIS LABORERS' AND	)	
EMPLOYERS HEALTH AND WELFARE	)	
FUND; NECA-IBEW WELFARE TRUST	)	
FUND; MIDWESTERN TEAMSTERS	)	
HEALTH AND WELFARE FUND; THE	)	
WELFARE FUND OF TEAMSTERS	)	
LOCAL UNION 863; PLUMBERS AND	)	CIVIL ACTION No. 06-CV-1818
PIPEFITTERS LOCAL UNION 630	)	
WELFARE TRUST FUND; CLEVELAND	)	JUDGE JOHN W. DARRAH
BAKERS AND TEAMSTERS HEALTH	)	
AND WELFARE FUND; ELECTRICAL	)	MAGISTRATE JUDGE
WORKERS BENEFIT TRUST FUND; FIRE	)	GERALDINE SOAT BROWN
& POLICE RETIREE HEALTH CARE	)	
FUND, SAN ANTONIO; LABORERS'	)	
DISTRICT COUNCIL BUILDING AND	)	
CONSTRUCTION HEALTH AND	)	
WELFARE FUND; LABORERS'	)	
DISTRICT COUNCIL HEAVY AND	)	
HIGHWAY UTILITY HEALTH AND	)	
WELFARE FUND; and NEW YORK CITY	)	
POLICE SERGEANTS BENEVOLENT	)	
ASSOCIATION HEALTH & WELFARE	)	
FUNDS, individually, and on behalf of all	)	
others similarly situated,	)	
Plaintiffs,	)	
v.	)	
PFIZER INC.,	)	
Defendant.	)	

**PLAINTIFFS' REPLY IN FURTHER SUPPORT OF THEIR AMENDED OBJECTIONS TO  
MAGISTRATE JUDGE BROWN'S ORDER DATED NOVEMBER 14, 2007 DENYING  
PLAINTIFFS' MOTION TO MODIFY DISCOVERY**

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Plaintiffs file this reply in opposition to Defendant Pfizer Inc's Opposition to Plaintiffs' Amended Objections to Magistrate Judge Brown's Order Dated November 14, 2007 (the "Def. Br.").

### INTRODUCTION

Magistrate Judge Brown's November 14 Order (the "Order") must be vacated because it requires Plaintiffs to produce documents that they do not have, requires production of information that has either no, or at most remote, relevance to the claims and defenses at issue, and, if implemented, would impose an extraordinary burden on Plaintiffs and their counsel that cannot be justified under Rule 26 of the Federal Rules of Civil Procedure. Pfizer's brief in opposition to Plaintiffs' appeal of the November 14 Order does nothing to change these points.

As an initial matter, Magistrate Judge Brown's discovery order resolves an issue of law – *i.e.*, the appropriate scope of Rule 26 – and is therefore subject to non-deferential, plenary review. Moreover, the Order applied an erroneous "impossibility" standard in evaluating Plaintiffs' access to and burden in obtaining the information ordered produced. Even Pfizer does not dispute this point.

More importantly, the Magistrate Judge completely misallocated the relevant burden of proof when determining that Plaintiffs controlled the information that is the subject of the Order. In moving to compel production of individual patients' lipid profiles, it was *Pfizer's burden* to prove that, as a legal matter, *each* of the individual Plaintiffs have sufficient "custody or control" over the underlying medical records so as to require their production. Pfizer offered but a single web page regarding a single Plaintiff and not one scintilla of evidence establishing "control" by any other named Plaintiff. The Magistrate Judge's rationale - that Plaintiffs did not demonstrate that it was "impossible" to obtain individual medical records - turned the applicable burden of proof completely on its head. Magistrate Judge Brown's November 14 Order, thus, is the product of a clear error of law and must be reversed for this reason alone.

As a simple matter of fact, *Plaintiffs do not have custody of the individual medical records that Pfizer seeks*. The mere fact that one named Plaintiff was able to obtain the cooperation of some – but certainly not all – of the physicians who provided care to some of its members so as to produce a limited number of medical records does nothing to demonstrate either that the one Plaintiff or any of the other Plaintiffs have legal control over those medical records. In its response, Pfizer points to nothing in the record before Magistrate Judge Brown

that can justify its bald assertion that every Plaintiff has sufficient “control” over the individual lipid profiles of their plan participants so as to require Plaintiffs to produce that information.

Even if, theoretically, Pfizer had presented sufficient evidence that could justify a finding that Plaintiffs have legal “control” over the medical records of their plan participants – and it did not – the simple fact is that the specific lipid profiles of Plaintiffs’ plan participants have nothing to do with any theory of liability articulated in the Second Amended Complaint (“SAC”) or any defense thereto. Pfizer does not – and cannot – explain how the individual lipid profiles of patients who took Lipitor have any bearing on Plaintiffs’ claims that Pfizer’s fraudulent marketing of Lipitor artificially inflated the price for *every* prescription of Lipitor provided to every patient, regardless of lipid levels. Plaintiffs do not seek damages based on *any* individual “off-label” prescriptions. Instead, Pfizer simply relies on Magistrate Judge Brown’s observation that the SAC still refers to Pfizer’s illegal “off-label” marketing as justification for demanding access to the individual medical records of Plaintiffs’ plan participants. That argument, however, is a *non sequitur*. Pfizer’s illegal “off-label” marketing, Plaintiffs allege, was part of its overall scheme to fraudulently increase the market and price of Lipitor. This was the precise reason that Plaintiffs sought leave to file the SAC in the first place. Magistrate Judge Brown’s determination that the filing of the SAC does not change the appropriate scope of discovery in this case completely disregards the fact that, in granting the motion for leave to file the SAC, this Court accepted Plaintiffs’ rationale for doing so.

Finally, even if Plaintiffs had “control” over both the medical records and the individual lipid profiles therein (and they do not), and even if the individual plan participants’ lipid profiles were somehow relevant to the claims or defenses at issue in this case (and they are not), the burden of producing this information is extraordinary and cannot be justified when weighed against whatever marginal value this information could provide to Pfizer. Pfizer’s argument that Plaintiffs’ complaint of undue burden is unsupported is disingenuous. Magistrate Judge Brown’s dismissal of this undue burden is unsupportable as a matter of law. Pfizer itself was involved in the process leading to the production of medical records for one Plaintiff fund. Pfizer knows full well the extraordinary efforts that went into obtaining the limited documents that Plaintiffs were able to produce. Magistrate Judge Brown’s mere observation that such production was not “impossible” completely misses the point. She did not, as required by Rule 26, engage in an appropriate analysis that weighed the extraordinary burden such production would require

against Pfizer's need for such information in the preparation of its defense. In its brief to this Court, Pfizer does not even pretend that the Magistrate Judge performed this required analysis. Pfizer merely relies on its bald – an incorrect – claim that Plaintiffs' claim of undue burden is illusory. *See* Def. Br. at 15.

For these reasons, as more fully set forth below, Magistrate Judge Brown's November 14 Order should be vacated.

### ARGUMENT

#### **I. PLAINTIFFS HAVE MET THE APPLICABLE STANDARD UNDER RULE 72(a) TO MODIFY THE ORDER**

Initially, Pfizer argues that the Objections fail to meet the applicable standard for granting reversal of the Order under Rule 72. Def. Br. at 5-7. Pfizer's argument assumes that a deferential standard applies. Pfizer ignores that the Order resolves legal issues – i.e. the appropriate scope of Rule 26, - and misses the key point that the plenary standard of review applies. As explained in Plaintiffs' Objections, "the Order makes a legal determination that evidence of off-label payments remains discoverable under Rule 26(b)(1). The Order is therefore subject to plenary review." Pl. Br. at 5.<sup>1</sup>

Rule 72(a) empowers the district court to "modify or set aside any portion of the magistrate judge's order found to be clearly erroneous or contrary to law." The "'clearly erroneous' standard applies to factual findings and discretionary decisions made in connection with non-dispositive pretrial discovery matters." *F.D.I.C. v. Fidelity & Deposit Co. of Maryland*, 196 F.R.D. 375, 378 (S.D. Cal. 2000). Where a magistrate's findings are based on legal conclusions and not findings of fact the "clearly erroneous standard does not apply" and the

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<sup>1</sup> The parties filed a Joint Motion to Stay Plaintiffs' compliance with the Order on December 13, 2007. [Dkt. No. 177]. The Joint Motion requested a stay of Plaintiffs' obligation to comply with the Order until ten days from a ruling on Plaintiffs' Objections or a ruling on Pfizer's pending motion to dismiss (which is itself stayed pending a ruling on Pfizer's Motion for Transfer), *whichever is later*. Magistrate Judge Brown granted the Joint Motion to Stay on December 14, 2007. However, Magistrate Judge Brown's December 14, 2007 Minute Order granted the stay only through a ruling on Plaintiffs' Objections. On December 19, 2007, Plaintiffs filed an Unopposed Motion and Incorporated Memorandum of Law for Clarification of Magistrate Judge's December 14, 2007 Minute Order to incorporate the "whichever is later" language from Joint Motion to Stay. On December 21, 2007, Magistrate Judge Brown issued an order denying Plaintiffs' Unopposed Motion for Clarification and reiterated that compliance with the Order be stayed until 10 days from a ruling on Plaintiffs' Objections. *See* [Dkt. No. 186]. The December 21, 2007 order further stated that any request for a stay to comply with the Order which is tied to the motion to dismiss must be presented to this Court.

scope of review “is plenary.” *See e.g., Jernryd v. Nilsson*, 117 F.R.D. 416, 417 (N.D. Ill. 1987). *See also Fidelity Deposit*, 196 F.R.D. at 378 (“The ‘contrary to law’ standard, however, permits independent review of purely legal determinations by the magistrate judge”). “[E]videntiary rulings typically pose questions of law, and discovery rulings that are dependent on evidentiary admissibility or likely admissibility do likewise.” *Phillips v. Raymond Corp.*, 213 F.R.D. 521, 525 (N.D. Ill. 2003).

Since Plaintiffs’ theory of liability and damages was completely altered with the filing of the SAC, the discovery called for by the Order necessarily required Magistrate Judge Brown to make the *legal* determination that information relating to off-label prescriptions is still relevant to the parties’ claims and defenses under Rule 26. *See* Order at 4 (stating information relating to “improper prescriptions for which Plaintiffs paid remains discoverable”). Since Magistrate Judge Brown’s determination involved a legal question – whether the evidence demanded by Pfizer remains discoverable under the theory of the SAC – the appropriate standard of review for the Order is plenary.<sup>2</sup> However, even if the Court adopts Pfizer’s arguments in support of the “clearly erroneous” standard, for the reasons stated herein the Plaintiffs’ Objections must be sustained.

## **II. THE ORDER VIOLATES RULE 26 BY REQUIRING THE PRODUCTION OF DISCOVERY PURSUANT TO AN ABANDONED THEORY OF LIABILITY AND DAMAGES**

Under Rule 26(b)(1), discovery is limited to the production of information “that is relevant to the claim or defense of any party . . . [or which] appears reasonably calculated to lead to the discovery of admissible evidence.” *See Aramark Educ. Res.*, 206 F.R.D. 459, 461 (M.D. Tenn. 2002) (“The threshold issue in any discovery dispute is determining whether the requested

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<sup>2</sup> Defendant’s reliance on *Jackson v. City of Chicago, et al.*, No. 03 C 8289, 2006 U.S. Dist. LEXIS 56675 (N.D. Ill. Jul. 31, 2006), for the proposition that a district court rejected challenges to a ruling from Magistrate Brown under the clearly erroneous standard of review, and therefore the clearly erroneous standard is the appropriate standard here (Def. Br. at 6), is baseless. *Jackson* contains no indication that the parties disputed whether the plenary or clearly erroneous standard applied to Magistrate Judge Brown’s ruling. At its core, *Jackson* simply upheld an order requiring more detailed responses to discovery requests. *Jackson*, 2006 U.S. Dist. LEXIS 56675, at \*34 (“Plaintiff has not offered any standard by which to assess the putative clear error in Judge Brown’s order except for the claim that the level of detail had not been required in the prior experience of Ms. Jackson’s attorneys”). Here, Plaintiffs argue that the discovery required by the Order is irrelevant to the liability and damages theories Plaintiffs have pled in the SAC and is not likely to lead to the discovery of admissible evidence. Magistrate Judge Brown’s ruling that off-label payment information falls within the SAC’s theories is thus a legal determination. *Jackson* is inapplicable.

discovery meets the requirements of Federal Rule of Civil Procedure 26 regarding relevance”). Accordingly, by its very language, Rule 26 does not allow for discovery wholly unrelated to parties’ claims and defenses. The Order compels production of exactly the type of discovery that Rule 26 excludes from its scope.

**a. Under the Theory of Liability Articulated in the Operative Complaint Detailed Information About Individual Off-Label Lipitor Prescriptions Is Irrelevant**

Pfizer argues that the Order is not erroneous because Magistrate Judge Brown determined that the theory pled in the SAC is similar to the theory of liability and damages under the First Amended Complaint (“FAC”), and therefore, requiring the identification of off-label payments falls within Rule 26. *See* Def. Br. at 7-11. Magistrate Judge Brown’s determination in this regard is flatly incorrect. Had Magistrate Judge Brown fully considered the rationale underlying Plaintiffs’ motion seeking leave to file the SAC and the District Court’s granting of Plaintiffs’ motion for leave to file the SAC, she could not – as she did – have concluded that the FAC’s theory overlapped with the theory of liability and damages in the SAC. Simply stated, Magistrate Judge Brown’s perceived similarity between the FAC and the SAC is at odds with this Court’s decision to permit Plaintiffs to file the SAC and Plaintiffs’ repeated statements disavowing any claims for damages for off-label prescriptions *qua* off-label prescriptions.<sup>3</sup>

The Court is well aware of the facts that drove the Plaintiffs to seek leave to file the SAC. As stated in the Motion for Leave [Dkt. No. 113-3]:

Plaintiffs . . . seek leave to file the SAC to *modify their damages theory and thereby* off-label prescriptions resulting from what Plaintiffs allege was Pfizer’s illegal off-label marketing scheme. *Demonstrating that Lipitor prescriptions were off-label entails, at some level, collection and examination of individual medical records. Proceeding on that basis is extremely inefficient and enormously burdensome.* Another court, describing the court’s “enormous frustration” with the substantial hurdles inherent even in highly meritorious off-label marketing cases, instructively stated: “...I think the pharmaceutical

<sup>3</sup> In terms of pleading damages under the FAC, as stated in Pl. Br. at 2, “Plaintiffs intended to establish damages under . . . [the FAC] through the use of statistical modeling showing an increase in the number of Lipitor prescriptions caused by or attributable to Pfizer’s illegal marketing practices.” Moreover, the SAC quotes Pfizer representatives who stated that Lipitor should be used by “about 79 million, or 40 percent of all adults.” SAC ¶152. Given that “NCEP has estimated that approximately 37 million people are eligible for statin drug therapy under ATP III” (SAC ¶153), Pfizer necessarily needed to expand its market for Lipitor to reach its stated goal of 40% of all adults through improper means. Accordingly, Pfizer’s own words provide a sufficient good faith basis to assert the claims pled in the FAC. *Compare* SAC ¶152-53 *with* Def. Br. at 1.

companies take advantage of this. They know, just based on aggregate marketing data, that they bump up or boost up the sales. But in a civil case, it can take you five years to unravel this stuff; and if I could have found an appropriate vehicle to have ordered restitution to the third-party payors, I would have done it.” *United States v. Schering Sales Corporation*, Crim. No. 06-10250-PBS, Transcript of Sentencing Hearing, Jan. 17, 2007, at 22-23 (Sairis, J.) (attached hereto as Exhibit A). This case, and the course of discovery so far, exemplifies the reasons for the *Schering Sales* court’s “enormous frustration” in trying to bring off-label pharmaceutical marketers to brook.

Motion for Leave at 1. (emphasis added). *Compare id.* with Def. Br. at 8.

The central reason Plaintiffs offered for seeking leave to file the SAC was the unrealistic burden needed to prove liability and damages under the theory of the FAC (as interpreted by Magistrate Judge Brown). *See* Order at 3 (discussing Plaintiffs’ motivation for seeking leave to file the SAC). At the September 4, 2007, hearing on Plaintiffs’ motion for leave, Plaintiffs’ counsel stated, “I don’t want there to be any mistake whatsoever. Our position is that the burdensome doctor-by-doctor, fund-participant-by-fund-participant discovery that Pfizer so much wants us to do because they know it’s impossible *would be unnecessary under our new theory.*” Exhibit A at 8 (emphasis added). Ruling from the bench, the Court granted Plaintiffs’ motion for leave to file the SAC.

The Order, and Pfizer’s Opposition, completely ignore the District Court’s consideration of Plaintiffs’ shift in theories between the FAC and the SAC. Plaintiffs have consistently and forthrightly explained why pursuing the theory pled in the FAC could not be accomplished under Magistrate Judge Brown’s rulings. As Plaintiffs explained to this Court, they filed the SAC to alter the theory of liability underpinning the FAC. Now the Order comes full circle and requires Plaintiffs to produce discovery under a theory they openly admitted would be withdrawn and that they did withdraw with the filing of the SAC. Had this Court determined that filing the SAC would serve no practical purpose it could have denied Plaintiffs’ motion for leave on futility grounds – as Pfizer urged. However, the District Court granted leave to amend and thus permitted Plaintiffs to amend the theory of liability.<sup>4</sup>

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<sup>4</sup> *See* Exhibit B at 20 (Magistrate Judge Brown states that the decision to change the theory of the case “is something you will have to take up with Judge Darrah”). Plaintiffs did exactly what Magistrate Judge Brown suggested by filing a motion for leave to file the SAC. The Court granted Plaintiffs’ motion for leave on September 4, 2007.

Clearly, the law does not preclude Plaintiffs from making a strategic decision to amend the theory of a case in order to avoid an unanticipated or unduly onerous evidentiary burden. *Cf. Serfecz v. Jewel Food Stores, Inc.*, No. 92 C 4171, 1997 WL 543116, at \*6 (N.D. Ill. Sept. 2, 1997) (“parties always amend their pleadings for strategic purposes. Indeed, adding a claim or a defense would be a pointless exercise if the amendment did not somehow brighten the movant's prospects in the litigation”).<sup>5</sup>

In its opposition, Pfizer seeks to support the Order by noting that Magistrate Judge Brown cited to paragraphs in the SAC which refer to Pfizer's off-label promotion of Lipitor. Def. Br. at 7 (citing Order at 5). But references in the SAC relating to Pfizer's scheme to *promote* Lipitor for off-label uses are relevant to the theory of the SAC only to the extent that they provide one example of Pfizer's scheme to inflate the *price* of Lipitor. As noted *supra* n.3, Pfizer's representatives have themselves made statements showing Pfizer's intention to expand the market for Lipitor. Accordingly, whether or not each Plaintiff actually paid for an off-label use of Lipitor is irrelevant under the SAC and therefore not discoverable under Rule 26. The act of paying for *any* Lipitor prescriptions (on or off-label) creates the injury for which the SAC is seeking recovery.<sup>6</sup>

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<sup>5</sup> Moreover, as the masters of the complaint Plaintiffs are entitled to frame the theory of recovery they wish to pursue. Neither a court nor a defendant is permitted to recast a plaintiff's theory. *See Scott Aviation, Inc. v. DuPage Airport Auth.*, 393 F. Supp. 2d 638, 646 (N.D. Ill. 2005) (“Plaintiffs are the master of their complaint and are proceeding under their chosen legal theories”). Given the operative theory, which does not claim damages for off-label payments, continued insistence that off-label prescriptions are at the core of Plaintiffs' case is erroneous – especially since Plaintiffs have affirmatively and repeatedly disavowed this theory. *Cf. In re Initial Public Offering Sec. Litig.*, 241 F. Supp. 2d 281, 332-33 (S.D.N.Y. 2003) (“It must be remembered, however, that Plaintiffs are the master of their complaint and ‘neither this Court nor the defendant have the right to redraft the complaint to include new claims.’ Defendants must take the Complaints as they are written”) (citations omitted). Here, the parties are bound to proceed under the SAC, which abandoned a theory of damages based on payments made by third-party payors for off-label payments for Lipitor. Under the theory of liability of the operative complaint, the SAC, that the clearly erroneous nature of the Order comes to light.

<sup>6</sup> Pfizer inappropriately clings to verbiage of Pfizer's scheme to promote Lipitor for off-label uses to argue that the theory of the SAC is similar to the FAC. Def. Br. at 8. To the extent any ambiguity still exists about the SAC, Plaintiffs again reiterate that they have abandoned any claims for damages for the number of off-label payments made for Lipitor and are instead seeking to recover overpayments made for each prescription of Lipitor paid for by Plaintiffs during the Class Period. *See Exhibit B* at 19-20 (Plaintiffs' counsel stated that under the SAC Plaintiffs would “change the theory of damages” to a “simple price theory” and that “[n]o longer [is there] a focus on a numerical quotient of how much the off-label market increased as a result of off-label prescriptions and then try to measure that. . .”).

For example, assuming, *arguendo*, that none of the Funds paid for an off-label use of Lipitor, under the SAC's theory, such Funds are nevertheless injured and would be entitled to recover damages. This example illustrates the Magistrate Judge's erroneous understanding of the SAC. See Def. Br. at 8; Order at 5. Under Magistrate Judge Brown's reasoning, "the claim that Plaintiffs were injured because they paid for unwarranted Lipitor prescriptions did not disappear with the filing of the Second Amended Complaint." Order at 5. This conclusion is wrong. Under SAC, Plaintiffs were damaged by paying for any prescriptions of Lipitor at artificially inflated prices, not because they may have paid for "unwarranted" prescriptions. Third-party payors that did not pay for off-label uses of Lipitor nevertheless suffered damages under the SAC. Pfizer's purported need to obtain this information in order to "defend against the Funds' claims" (Def. Br at 9) therefore evaporates and the Order clearly exceeds the bounds of Rule 26.<sup>7</sup> See *U.S. v. Seaga Corp.*, No. 00 C 50389, 2002 WL 31045388, at \*2 (N.D. Ill. Sept. 11, 2002) (refusing to order production of documents that are unrelated to a party's claim). See also *Aramark Educ. Res.*, 206 F.R.D. at 461 (noting Rule 26's "discovery boundary").<sup>8</sup> One party's unilateral claim that information is relevant is not sufficient to order its production in all cases. See *Patterson v. Avery Dennison Corp.*, 281 F.3d 676, 681 (7th Cir. 2002) ("Rule 26(b)(2) of the Federal Rules of Civil Procedure empowers district courts to limit the scope of discovery if 'the discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive.'").<sup>9</sup>

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<sup>7</sup> Pfizer's argument that since Plaintiffs are "aggressively seeking prescription information, *to the extent it exists*, from Pfizer and from a nonparty provider of prescription data and analysis" (Def. Br. at 10) (emphasis added), information relating to off-label prescriptions must necessarily be relevant – is a red herring. The Order does not compel the production of information kept in the ordinary course of the Plaintiffs' business. Rather, the Order requires Plaintiffs to conduct an extremely invasive review of personal non-party medical records, have the records reviewed by experts and then create a report of payments for off-label Lipitor uses.

<sup>8</sup> Pfizer's "discovery rights" (Def. Br. at 9) are defined by the limitations of Rule 26. Defendants are not entitled to pursue discovery outside the bounds of Rule 26 merely because it creates an enormous burden on the part of the responding party. See e.g., *Patterson*, 281 F.3d at 681 (upholding district court's refusal to permit deposition where other less expensive means to obtain information were available to a party).

<sup>9</sup> Defendant's attempt to downplay the holding in *Zyprexa* and the use of statistical modeling to prove damages in third-party payor cases (Def. Br. at 11) is misplaced. In *Zyprexa*, Judge Weinstein responds to nearly the identical argument being raised by Pfizer regarding the use of statistical modeling by stating, "Defendant argues that plaintiffs' use of aggregate proof, rather than individualized proof, to establish reliance is impermissible. This assertion is without merit." *In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571, 578-79 (E.D.N.Y. 2007). Pfizer's assertion here that statistical modeling cannot be used as a

**b. The Order Misapplied The Applicable Standards For Evaluating Burden and Control**

Pfizer incorrectly argues that “the Funds have not identified any mistake in Judge Brown’s finding that the Funds have control over the information necessary to identify any allegedly off-label Lipitor prescriptions for which they have paid.” Def. Br. 13.

First, as stated in Plaintiffs’ Objections (*see e.g.*, at 9-10), in evaluating whether the production of individual prescription information posed an undue burden, Magistrate Judge Brown erroneously determined that since production of the demanded information was not “*impossible*,” production could be ordered under Rule 26. Impossibility is *not* the standard for determining “undue burden” under the Federal Rules. Pfizer did not respond to this argument.

Second, in holding that Plaintiffs controlled the documents needed to produce information of off-label payments, the Order ignores the fact that as the party seeking production, it was Pfizer’s burden to prove – not Plaintiffs’ burden to disprove – Plaintiffs’ control over the documents needed to identify off-label payments of Lipitor. *See, e.g., Sparks Tune-Up Centers, Inc. v. Panchevre*, No. 90 C 4369, 1991 WL 101667, at \*3 (N.D. Ill. Jun. 4, 1991) (“the party which brings the motion to compel has the burden of establishing that the non-movant has control of the requested documents”). The Order simply accepted Pfizer’s glib characterization of one document from one fund as sufficient to determine that every other fund controlled the information it was ordering to be produced. As explained to Magistrate Judge Brown during an oral argument, Plaintiffs do not control the information she is ordering them to

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matter of law is simply false. At the 12th Annual American Conference Institute Drug and Medical Device Litigation Conference held December 12-14, 2007 at the Waldorf Astoria in New York City, a panel entitled “Consumer Fraud Claims and Class Actions: Defending Drug and Device Manufacturers at Every Stage of Litigation” on December 14, 2007, which included Pfizer’s counsel, described as a “very dangerous trend” the use of economic aggregate modeling, discussing *In re Neurontin Marketing and Sales Practices Litig.*, 244 F.R.D. 89 (D. Mass. 2007), as containing a “roadmap” for overcoming obstacles to obtaining class certification in such a case. Pfizer’s attack against Plaintiffs’ intended use of statistical modeling to establish damages (Def. Br. at 10) was raised in Pfizer’s Memorandum of Law in Opposition to Plaintiffs’ Motion for Leave to File a Second Amended Complaint [Dkt. No. 121] at pgs. 2, 5-6, 11-12 & n.3 (citing *Prohias I*, *Prohias II*, *Heindel*, *Schering-Plough*, and *Rivera*). Moreover, Pfizer’s Memorandum of Law in Opposition to Plaintiffs’ Motion for Leave to File a Second Amended Complaint argued that granting Plaintiffs leave to amend would be futile because their overpayment theory would not survive a Rule 12 motion. Plaintiffs responded to this argument in their Reply to Pfizer’s opposition brief. *See* [Dkt. No. 123] at pgs. 8-12 & n.8. The Court granted Plaintiffs leave to file the SAC on September 4, 2007 [Dkt. No. 126], thus implicitly rejecting the argument Pfizer recycles here.

produce.<sup>10</sup> Thus, where merely Pfizer claims Plaintiffs control the necessary information needed to respond, Plaintiffs deny such control, and Pfizer fails to introduce any evidence establishing such control, Pfizer has not met its burden to establish control. Magistrate Judge Brown's acceptance of Pfizer's arguments, while dismissing out of hand Plaintiffs' arguments to the contrary, is erroneous when the burden is on Pfizer to establish control.

**i. Requiring Plaintiffs To Produce Evidence Of Individual Prescriptions Is Unduly Burdensome**

Pfizer makes two points in arguing that Plaintiffs have not demonstrated that compliance with the Order imposes an undue burden. *See* Def. Br. at 14-15. First, Pfizer claims that the Order fully considered the relevant factors under Rule 26(b)(2)(C)(iii). *See* Def. Br. at 14-15. Second, Pfizer suggests that Plaintiffs have not provided sufficient factual support for their burden argument. *See* Def. Br. at 14. Both arguments are wrong.

Rule 26(b)(2)(C)(iii) set forth specific criteria courts must evaluate when determining whether discovery imposes an undue burden. Specifically, Rule 26(b)(2)(C) states, "[T]he court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that . . . (iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues."<sup>11</sup>

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<sup>10</sup> *See e.g.*, Exhibit C at 13-15; *See also* Exhibit D at 11-12 (explaining process for gathering information needed to determine if prescriptions were for off-label uses)

<sup>11</sup> Here, in concluding that Plaintiffs would not face an undue burden by providing off-label prescription information, the Order states:

Given the large sums of money that Plaintiffs seek, it is understandable that Pfizer wants to know whether Plaintiffs' own experiences support their claims. Particularly striking is the fact that the fund selected by the Plaintiffs to provide the first answer to Pfizer's interrogatory identified at most 6 individuals. As this court expressed at the hearing on August 28, 2007, the parties' judgments about how to proceed, including, for example, whether settlement is possible, depend on getting a firm grasp of the facts behind the allegations.

Order at 8; Def. Br. at 14. Absent from the Magistrate Judge's analysis is an analysis of the parties' resources and the importance of the issues at stake in the action. Plaintiffs are Taft-Hartley funds organized to serve the interests of their members. Plaintiffs simply do not have the resources necessary to complete a task on the scale contemplated by the Order. Moreover, even if Plaintiffs were blessed with unlimited resources, the information demanded by the Order, while arguably relevant to the theory of liability articulated in the FAC, is irrelevant to proving liability or damages under the theory of the operative complaint.

As an initial matter, Pfizer offers no response to Plaintiffs' argument that the Order misapplied Rule 26 by stating that "Plaintiffs have not demonstrated that it is *impossible* to produce the information about what prescriptions they paid for and which of those they consider to have been the unnecessary result of improper marketing" (Order at 7 (emphasis added)). Rule 26's analysis turns on whether "the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues" – not whether production of the demanded discovery is theoretically possible. *See* Fed. R. Civ. P. 26(b)(2)(C)(iii). The Order's impossibility standard violated the applicable Rule 26 analysis for burden.

Second, Plaintiffs repeatedly have stated, under the pain of Rule 11, that they will face undue burden if forced to comply with the Order. During a hearing before Magistrate Judge Brown, Plaintiffs' counsel stated: "Your Honor said that Rule 11(b) governs attorney's representations to the court. I've made representations to this Court about the difficulty and burdensomeness of getting these nonparty documents. I stand by those." Exhibit E at 18. Plaintiffs have not, as Pfizer suggests, raised the burden of collecting the necessary medical records to identify off-label uses of Lipitor without any factual support or without actually experiencing the pains of compiling a list of off-label prescriptions. *See* Def. Br. at 14 ("The Funds do not address these findings, other than to assert through the unsworn, conclusory statements of their attorneys in a brief, that '[t]he burden imposed on Plaintiffs by the Order is enormous"). Plaintiffs' counsel offered in open court to provide an affidavit detailing the burden of collecting information needed to determine if payments were made for off-label uses of Lipitor: "we'd be happy to provide an affidavit if that's necessary." Exhibit F at 20. No affidavits were requested.

Further, Plaintiffs' experience in collecting information relating to payments for off-label uses for the one test fund gives Plaintiffs firsthand knowledge of the burden needed to comply with the Order. Pfizer is aware of the difficulty Plaintiffs endured in order to obtain the necessary information from the test fund. In fact, Pfizer claimed the right, which the Magistrate Judge blessed, to participate in drafting the medical records request letter to physicians after physicians who had received Plaintiffs' completely accurate letter called Pfizer to ask what was going on. Merely sending records requests, however, did virtually nothing to produce records.

Plaintiffs were forced to devote additional time to follow up with non-responsive physicians, explain the urgency of the matter, stress the importance of the demanded information and ultimately wait to see if the physicians would comply. Accordingly, Plaintiffs' undue burden arguments if forced to comply with the Order are not theoretical, "illusory" or "exaggerated."<sup>12</sup> They are based on firsthand knowledge of the process.<sup>13</sup>

**ii. Pfizer Failed to Meet Its Burden To Establish Plaintiffs' Control Over The Documents Needed to Identify Off-Label Payments Of Lipitor**

As noted in Plaintiffs' Objections (at 6), the burden of establishing control over the documents being sought rests with the demanding party, here Pfizer. *See, e.g., Sparks Tune-Up Centers, Inc.*, 1991 WL 101667, at \*3 (reversing magistrate judge's motion to compel where party did not control documents magistrate ordered to be produced); *id.* ("the party which brings the motion to compel has the burden of establishing that the non-movant has control of the requested documents"). Addressing whether the Funds control the information necessary to identify off-label prescriptions, the Order incorrectly equates a contractual right to access information by one fund identified by Pfizer, with control over the information needed to comply with the Order by all the funds. *See* Order at 7.

Here, Plaintiffs simply do not have custody of the personal medical records of all their plan participants in order to identify each individual off-label payment for Lipitor. Pfizer's own representations to Magistrate Judge Brown did not offer any arguments establishing control over such documents. Before Magistrate Judge Brown, Pfizer's counsel merely stated, "Their own plan documents, and it's all in our papers, specifically say: We, as the insurer -- they're essentially an insurance company -- have a right to *request* medical information. . . ." Exhibit H at 34 (emphasis added). As Pfizer surely knows, requests for compliance can easily can be denied. A party lacking the power to compel production from others should not be compelled by the Court to produce such information. *See Sparks Tune-Up Centers, Inc.*, 1991 WL 101667, at

<sup>12</sup> *See* Def. Br. at 15. Noting the burden of providing the information compelled by the Order during the August 28, 2007 hearing, Judge Brown noted, "If you're successful [and Judge Darrah grants Plaintiffs' motion for leave to file the SAC], I would make a guess that you're going to argue that compliance with Interrogatory 3 is moot." Exhibit G at 25. In response, Plaintiffs' counsel stated "Yes, your Honor." *Id.* at 26.

<sup>13</sup> *See also* Exhibit B at 19 (describing burden of providing information for test fund); Exhibit A at 8 ("I don't want there to be any mistake whatsoever. Our position is that the burdensome doctor-by-doctor, fund-participant-by-fund-participant discovery that Pfizer so much wants us to do because they know it's impossible would be unnecessary under our new theory").

\*3 (“A party cannot be required to permit inspection of documents or things that he does not have and does not control.”) (citing Wright & Miller, Federal Practice & Procedure: Civil, § 2210 (1970)). As found in *Technical Concepts, L.P. v. Continental Mfg. Co.*, control over documents cannot be alleged generally, “the party bringing the motion must have a legal right to obtain the documents *on demand*.” No. 92 C 7476, 1994 WL 262119, at \*1 (N.D. Ill. Jun. 10, 1994) (emphasis added). Contrary to Pfizer’s hypothetical control arguments, Plaintiffs have stated in open court based on their experience with the test fund, that the Order, if implemented, would require Plaintiffs to affirmatively go out and obtain records needed to identify off-label prescriptions from third parties – *i.e.*, the physicians who treated Plaintiffs’ members. See Exhibit I at 22 (“[Pfizer is] asking . . . [Plaintiffs] to get . . . [information] from nonparties who are not litigants and don’t have a direct interest in the case.”). Plaintiffs cannot merely open a file in their offices and provide the type of information compelled by the Order.

That some of the Plaintiffs’ plan documents may give a fund permission to *request* documents does not equate to a “right” of access to documents relating to specific *lipid profiles* of each of the plan participants and the right to compel such information. To distill a list of exclusively off-label payments, Plaintiffs must obtain the relevant medical records from uncooperative third-parties, analyze the information, and then create a list of potential recipients of off-label uses. The information needed to respond to the Order is simply not kept in the ordinary course of any Plaintiff’s business. Cf., *In re Remeron End-Payor Antitrust Litig.*, No. Civ. 02-2007 FSH, Civ. 04-5126 FSH, 2005 WL 2230314, at \*15 n.4 (D.N.J. Sept. 13, 2005) (noting that “End-Payor Plaintiffs and Plaintiff States were unable to obtain a list of potential class members for a direct mail campaign and instead had to *rely* on pharmacies and psychiatrists to forward notices to their customers and patients”) (emphasis added). Plaintiffs’ counsel provided the following example as one of the many hurdles faced by Plaintiffs when they attempted to secure members’ medical records during a hearing before Magistrate Judge Brown:

One other quick point, Your Honor, and then I’m done. Mr. Cheffo said: Well, they can do it. It’s not burdensome. Look at the Florida case. Look at the letters. Yes, indeed, those letters said we have the ability to do this, to get these documents, and a lot of doctors’ offices called and said: *No, you don’t*.

Exhibit J at 38 (emphasis added).<sup>14</sup> Accordingly, the holding of the Order is erroneous because Pfizer failed to establish that Plaintiffs control the documents Pfizer seeks to compel.<sup>15</sup>

### iii. Pfizer Failed to Address Plaintiffs' Arguments Regarding the Hurdles Imposed By HIPPA and State Privacy Laws

As stated in Plaintiffs' Objections (Pl. Br. at 7), because the medical records the Order compels are in the hands of third-parties who are scattered around the country, HIPPA and various states' privacy regulations creates an independent basis for vacating the Order. Pfizer's response to this argument (Def. Br. at 13) simply fails to address the concerns raised by Plaintiffs.

The third-parties holding the records the Order compels are located in no fewer than ten different states. These medical providers are not only subject to HIPPA disclosure restrictions but are also subject to state privacy regulations that are – in some cases – more restrictive than HIPPA. *See Remeron*, 2005 WL 2230314, at \*15 n.4 (improperly producing medical records in violation of HIPPA “may subject the provider to civil and/or criminal penalties [under HIPPA].”). Assuming that the Order protects disclosing parties from liability under HIPPA, the Order – which is directed to Plaintiffs – does not protect third-parties from any liability if they disclose protected information in violation of their respective state's privacy laws. Pfizer's response to these legitimate concerns is to cite to the Seventh Circuit's decision in *Northwestern Mem'l Hosp. v. Ashcroft*, 362 F.3d 923 (7th Cir. 2004) (Def. Br. at 13) and conclude that Seventh Circuit precedent completely moots that concern. Based on a misapplication of *Ashcroft*, this argument misses the mark.

In *Ashcroft*, 362 F.3d 923, the Seventh Circuit addressed whether a subpoena recipient, who moved to quash the subpoena, was entitled to rely on Illinois law to withhold the production of certain medical records. *See id.* *See also National Abortion Fed'n v. Ashcroft*, 2004 WL 292079, at \*2 (noting that Northwestern moved to quash). *Ashcroft*, 362 F.3d 923, did not address the broader concerns Plaintiffs raise here, namely, how physicians can be given assurances that their voluntary disclosure of medical records does not – as a matter of law – run

<sup>14</sup> Compare *id.* with *Technical Concepts*, 1994 WL 262119, at \*1 (control over documents requires a “legal right to obtain the documents *on demand*.”) (emphasis added).

<sup>15</sup> Contrary to Pfizer's assertion (Def. Br. at 1), Plaintiffs have never conceded that they control the information needed to respond to the Order, as even a cursory review of the oral argument transcript reveals. *See e.g.*, Exhibit J at 38.

afoul of their obligations under their respective states' privacy laws in the absence of a subpoena issued by a court.<sup>16</sup> Moreover, unlike *Ashcroft*, 362 F.3d 923, where the responding party was served with a subpoena, Plaintiffs' have no legitimate recourse if physicians do not comply with Plaintiffs' request for the production of their penitents' medical records. If a subpoena is required to force compliance, no legitimate argument can be raised that Plaintiffs control the information compelled by the Order.<sup>17</sup>

### CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court sustain Plaintiffs' objections to Magistrate Judge Brown's November 14 Order.

DATED: December 27, 2007

Respectfully submitted,

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<sup>16</sup> *Ashcroft* noted that Illinois' privilege "does not govern in federal-question suits." 362 F.3d at 925. Here, the SAC asserts jurisdiction not only under RICO (which would provide a basis for federal question jurisdiction) but also under 28 U.S.C. 1332, based on diversity of citizenship. See SAC ¶21. On December 21, 2007, Magistrate Judge Brown issued an order stating that, *inter alia*, diversity jurisdiction is inapplicable here because Pfizer and one Plaintiff are both citizens of New York. [Dkt. No. 185] at 11 n.4. This observation overlooks the "Class Action Fairness Act" which amended Section 1332 to specifically permit diversity jurisdiction where "any member of a class of plaintiffs is a citizen of a State different from any defendant" and where certain other criteria are met. 28 U.S.C. 1332(d)(2)(A) (emphasis added). Accordingly, if the Court's jurisdiction over this action is based on diversity it is unclear whether *Ashcroft* even applies here. Assuming *Ashcroft* is applicable, Pfizer does not explain how the quoted language from *Ashcroft* applies when third-parties, who are not served with subpoenas, hold the necessary medical records needed to comply with the Order. Thus, whether *Ashcroft* would apply to permit Plaintiffs to produce medical records in their possession notwithstanding more restrictive Illinois privacy laws has nothing to do with whether Plaintiffs can force physicians in other jurisdictions to disregard the privacy laws of their respective states and produce documents to Plaintiffs for this action.

<sup>17</sup> Moreover, Pfizer's breezy contention that Plaintiffs have put their members' medical information "at issue" by filing this action (Def. Br. at 12) misconstrues the allegations of the SAC. The only issues here are: (1) whether Plaintiffs paid for any Lipitor prescriptions during the Class Period; (2) Pfizer's over-promotion of Lipitor; and (3) how Pfizer's actions affected the price Plaintiffs paid for Lipitor. The medical records of individual members are simply not an issue under the SAC. Additionally, the protective order referenced by Pfizer (Def. Br. at 12 n.13) was entered into under the theory pled in the FAC under which the disclosure of some medical records may have been required. Disclosure of individual medical records is not necessary under the SAC.

– and –

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# **EXHIBIT S**

UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

SOUTHERN ILLINOIS LABORERS' AND )  
EMPLOYERS HEALTH AND WELFARE )  
FUND; NECA-IBEW WELFARE TRUST )  
FUND; MIDWESTERN TEAMSTERS )  
HEALTH AND WELFARE FUND; THE )  
WELFARE FUND OF TEAMSTERS )  
LOCAL UNION 863; PLUMBERS AND )  
PIPEFITTERS LOCAL UNION 630 )  
WELFARE TRUST FUND; CLEVELAND )  
BAKERS AND TEAMSTERS HEALTH )  
AND WELFARE FUND; ELECTRICAL )  
WORKERS BENEFIT TRUST FUND; FIRE )  
& POLICE RETIREE HEALTH CARE )  
FUND, SAN ANTONIO, LABORERS' )  
DISTRICT COUNCIL BUILDING AND )  
CONSTRUCTION HEALTH AND )  
WELFARE FUND; LABORERS' DISTRICT )  
COUNCIL HEAVY AND HIGHWAY )  
UTILITY HEALTH AND WELFARE )  
FUND, NEW YORK CITY POLICE )  
SERGEANTS BENEVOLENT )  
ASSOCIATION HEALTH & WELFARE )  
FUNDS, and SIDNEY HILLMAN HEALTH )  
CENTER OF ROCHESTER )  
individually, and on behalf of all others )  
similarly situated, )

Plaintiffs, )

v. )

PFIZER INC., )

Defendant. )

NO. 06-CV-1818

JUDGE JOHN W. DARRAH

MAGISTRATE JUDGE  
GERALDINE SOAT BROWN

**PFIZER INC.'S MOTION TO COMPEL PLAINTIFFS  
TO PROVIDE DOCUMENTS, UNREDACTED CLAIMS RECORDS, AND  
RESPONSES CONCERNING PFIZER'S PROPRIETARY MATERIALS**

Defendant Pfizer Inc (“Pfizer”) hereby moves, pursuant to Rules 33, 34, and 37 of the Federal Rules of Civil Procedure (the “Rules”), to compel the Plaintiff Funds (collectively “Plaintiffs” or the “Funds”) to disclose the following discoverable information and documents: (1) long-overdue documents that Plaintiffs agreed to produce in response to Pfizer’s requests; (2) unredacted documents concerning the participants who filled Lipitor prescriptions; (3) a response to Pfizer’s lone interrogatory about the circumstances by which Plaintiffs obtained confidential, proprietary, and apparently misappropriated, internal Pfizer documents that Plaintiffs have relied on and cited in their pleadings; and (4) documents relating to Plaintiffs’ identification of purported improper off-label Lipitor prescriptions.

### **INTRODUCTION**

Plaintiffs have refused or otherwise failed to produce the foregoing categories of relevant information and documents despite Pfizer’s repeated requests, and despite their representations and promises many months ago. First, over a year after having agreed to provide documents responsive to several dozen targeted requests, the vast majority of Pfizer’s requests remain outstanding, and seven of the twelve Funds have produced fewer than 400 pages. Indeed, several of the Funds have produced less than 100 pages. Moreover, notwithstanding Pfizer’s continuous searches and continuing production of hundreds of thousands of pages in response to Plaintiffs’ ever-expanding requests, Plaintiffs have indicated that they are not even searching for the outstanding documents that they agreed to produce.

Second, only seven of the twelve Funds have actually produced Lipitor claim information in response to Pfizer’s requests. Of the seven, three have provided some participant information, including names and prescribing physicians, but four have improperly redacted participant names and other essential information and have refused to provide unredacted documents or electronic

files. This Court has already ruled that information about the Lipitor prescriptions for which Plaintiffs reimbursed participants is relevant and discoverable, including after Plaintiffs were granted leave to file a Second Amended Complaint asserting a modified “price inflation” theory of damages. Moreover, Plaintiffs’ counsel has conceded that the information is protected by the parties’ existing protective order. Indeed, it takes more effort to redact the information than to produce it. The four Funds, nevertheless, continue to refuse to disclose it, and five other Funds have yet to produce a single page of prescription information.

Third, Plaintiffs have refused to provide a substantive response to a lone interrogatory asking Plaintiffs to describe the circumstances under which they obtained over 2,200 pages of internal, confidential, proprietary, and likely misappropriated, Pfizer materials that they have incorporated into their pleadings, and produced during discovery. This information, on which Plaintiffs purport to base many of their allegations, is plainly relevant and, contrary to Plaintiffs’ contention, not protected work product. Indeed, the individuals involved in providing the documents to Plaintiffs are likely to be witnesses in this case and their identities cannot properly be shielded until Plaintiffs are ready to surprise Pfizer.

Fourth, Plaintiffs have refused to provide records relating to off-label Lipitor prescriptions they have identified or will identify pursuant to this Court’s orders. Plaintiffs’ refusal is inconsistent with the Court’s rulings and their own commitments in their discovery responses. Documents concerning the participants, as well as communications with any health care professional who identifies improper off-label prescriptions, are discoverable.

Pfizer has conferred with Plaintiffs' counsel numerous times by telephone, letter, and e-mail in good faith attempts to resolve these issues.<sup>1</sup> Plaintiffs, however, continue to refuse to provide the requested information. As established in more detail below, Plaintiffs' position is not supportable. Accordingly, Pfizer moves this Court to compel prompt and proper responses.

### **LEGAL STANDARD**

Pursuant to Rule 26, "[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party . . . ." Fed. R. Civ. P. 26(b)(1). Rule 37 allows a requesting party to "move for an order compelling an answer" to an interrogatory under Rule 33, or "compelling inspection in accordance with [a] request" for documents under Rule 34. Fed. R. Civ. P. 37(a)(2)(B). Where a request appears relevant, the objecting party bears the burden of showing why its objection or failure to respond is proper. *See Meyer v. S. Pac. Lines*, 199 F.R.D. 610, 612 (N.D. Ill. 2001); *accord Trading Techs. Int'l, Inc. v. eSpeed Inc.*, No. 04 C 5312, 2005 U.S. Dist. LEXIS 10686, at \*2 (N.D. Ill. Apr. 28, 2005). For example, where a party "resist[s] discovery as unduly burdensome, [it] must 'adequately demonstrate the nature and extent of the claimed burden' by making a 'specific showing as to how disclosure of the requested documents and information would be particularly burdensome.'" *Eley v. Herman*, No. 1:04-cv-416, 2005 U.S. Dist. LEXIS 30476, at \*2-3 (N.D. Ind. Nov. 21, 2005) (citation omitted).

### **ARGUMENT**

#### **I. PLAINTIFFS MUST PRODUCE LONG-OVERDUE DOCUMENTS**

Pfizer has previously documented the vast deficiencies in Plaintiffs' responses to Pfizer's requests for documents. *See Pfizer's Motion to Compel Plaintiffs to Provide Proper Responses*

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<sup>1</sup> Counsel for Pfizer, Mark S. Cheffo, conferred with counsel for the Funds, Stephen Grygiel, by telephone on: June 27, 2007, at 12:00 p.m. EST; July 20, 2007, at 3:30 p.m. EST; August 22, 2007, at 11:00 a.m. EST; and August 24, 2007, at 3:00 p.m. EST.

to Interrogatories and Requests for Production of Documents [D.E. 77]; Pfizer's Notice of Outstanding Discovery Disputes [D.E. 90]; Pfizer's Supplement to Notice of Outstanding Discovery Disputes [D.E. 91]. Pfizer withdrew its prior comprehensive motions to compel in June 2007, based on Plaintiffs' assurances, to Pfizer and to this Court, that proper discovery responses, already many months overdue, would be forthcoming. *See* 6/13/07 Minute Order [D.E. 92]. Plaintiffs, however, have not honored their commitment, and have proceeded as if Pfizer's discovery requests do not exist.

Over three months after Plaintiffs supplemented their written responses to Pfizer's document requests (which were served over a year ago to the Illinois Funds and over eight months ago to the added Funds), and agreed to produce numerous categories of admittedly relevant and discoverable documents, over half of the Funds have produced less than 400 pages of documents, and none of the Funds have produced documents in response to the majority of Pfizer's requests. In light of Plaintiffs' promises, the Court will likely be surprised to hear that after seventeen months of litigation, the Funds have produced:

- **Fire & Police Retiree Health Care Fund, San Antonio:** 0 pages
- **New York City Police Sergeants Benevolent Association Health & Welfare Funds:** a 19-page prescription drug program summary and a compact disk ("CD") containing redacted Lipitor claims information
- **The Welfare Fund of Teamsters Local Union 863:** 43 pages of redacted Lipitor claims information
- **Sidney Hillman Health Center of Rochester:** 83 pages of general plan documents<sup>2</sup> and a single page of claims information
- **Cleveland Bakers and Teamsters Health and Welfare Fund:** 118 pages of general plan documents

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<sup>2</sup> "General plan documents," as used herein, refers primarily to documents relating to fund formation (e.g., trust agreements and bylaws) and operation (e.g., summary plans (descriptions of plan benefits provided to participants) and contracts with pharmacy benefit managers).

- **Laborers' District Council Building and Construction Health and Welfare Fund:** 266 pages of general plan documents
- **Laborers' District Council Heavy and Highway Utility Health and Welfare Fund:** 269 pages of general plan documents
- **Plumbers & Pipefitters Local Union 630 Welfare Trust Fund:** 371 pages of Lipitor claims records
- **NECA-IBEW Welfare Trust Fund:** 1563 pages of general plan documents
- **Southern Illinois Laborers' and Employers Health and Welfare Fund:** 1793 pages of general plan documents and redacted pharmacy records and one CD of redacted claims records
- **Midwestern Teamsters Health and Welfare Fund:** 5005 pages of general plan documents and redacted pharmacy records
- **Electrical Workers Benefit Trust Fund:** 14,253 pages of claims records (non-Lipitor specific) produced on CD

In contrast to Plaintiffs' meager, and in some cases, non-existent, productions, Pfizer has produced approximately 500,000 pages of documents and is continuing to search for and produce additional documents in response to Plaintiffs' unfocused, and largely irrelevant, requests.

More specifically, despite Plaintiffs' promises to produce responsive documents, the following requests remain unanswered:<sup>3</sup>

- No. 7 (documents identifying any physician who prescribed Lipitor to a participant for an off-label purpose, as defined in the Amended Complaint<sup>4</sup>)<sup>5</sup>
- No. 9 (documents reflecting payments made for off-label Lipitor prescriptions)
- No. 10 (documents sufficient to determine the amount of damages alleged)
- No. 17 (documents regarding Fund's decision to include Lipitor on formulary)

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<sup>3</sup> Unless otherwise noted, these requests were first promulgated in Pfizer's First Request for Production of Documents, served June 6, 2006, on the Illinois Funds, and December 18, 2006, on the added Funds. The requests have been paraphrased herein. An example of the requests, and Plaintiffs' supplemented responses, is attached hereto as Exhibit A.

<sup>4</sup> Plaintiffs' Second Amended Complaint contains the same definition of "off-label" purpose.

<sup>5</sup> At Pfizer's repeated request, Plaintiff Plumbers & Pipefitters has provided this information in connection with its identification of participants whom it claims received off-label Lipitor prescriptions.

- No. 18 (documents regarding the possible removal of Lipitor from formulary)
- No. 19 (documents regarding Fund's initial determination to pay for Lipitor)
- No. 20 (documents reflecting any change in Fund's policy/practices/rules regarding Lipitor)
- No. 21 (documents provided to participants or physicians by Fund regarding reimbursement/payment for Lipitor)
- No. 22 (documents provided to participants or employers regarding this lawsuit)
- No. 23 (documents sufficient to identify the LDL level of each participant who received an off-label Lipitor prescription)
- No. 24 (documents sufficient to identify the ten-year cardiac risk profile for same)
- No. 26 (documents sufficient to identify each participant denied reimbursement for Lipitor)
- No. 28 (documents notifying any participant that claim for Lipitor was denied)
- No. 29 (documents containing any statement about Lipitor relied upon by Fund)
- No. 30 (any Lipitor ad or promotional piece relied upon by Fund)
- No. 31 (communications between Fund and PBMs regarding benefits provided)
- No. 32 (documents reflecting efforts by Fund to prevent off-label prescriptions of Lipitor)
- No. 33 (any Pfizer ad relied upon by any participant who filled an off-label Lipitor prescription)
- No. 34 (documents supporting the position that the NCEP Guidelines limit the Lipitor indication)
- No. 35 (documents sufficient to identify the type and number of risk factors for off-label participants)
- No. 37 (documents providing the name of each physician who has written a Lipitor prescription for any participant during the relevant time period)
- No. 39 (any joint prosecution or joint representation agreement among the parties)
- No. 40 (correspondence regarding off-label promotion or use between Fund and any other statin maker)
- No. 41 (documents containing calculations/analysis of number of off-label Lipitor prescriptions)
- No. 42 (documents provided to any public relations firm concerning this lawsuit)
- No. 43 (documents regarding any beneficial health effects received by off-label Lipitor patients)
- No. 45 (documents from physicians regarding the use of Lipitor by participants)

- No. 46 (copy of each Lipitor prescription paid for by Fund that was made for an off-label purpose)
- No. 47 (documents submitted by healthcare providers regarding off-label Lipitor prescriptions)
- No. 54 (documents sufficient to identify any accountant retained to assist with reimbursement for Lipitor)
- No. 56 (docs reflecting all meetings where presentation made to Fund or its employees regarding Lipitor)
- No. 59 (any annual or scheduled audits of benefits)
- No. 60 (documents regarding the nature and appropriateness of claims paid)
- No. 61 [1]<sup>6</sup> (publications provided by Fund to participants regarding health or wellness)
- No. 64 [4] (reports/recommendations/analysis provided by any consultant to trustees of Fund)
- No. 66 [6] (documents identifying name and dose of any medicine taken concomitantly with Lipitor by off-label participant)
- No. 67 [7] (documents identifying each participant who filled prescription for another statin before Lipitor)
- No. 68 [8] (documents identifying off-label participants' LDL, HDL, and triglyceride levels)
- No. 71 [11] (documents sufficient to determine that each allegedly off-label Lipitor prescription was written for a person who was a member of the class to which the plan pertains)
- No. 72 [12] (documents identifying individuals responsible for reviewing claims)
- No. 76 [16] (reports or analysis regarding Fund participants taking statins)
- No. 77 [17] (documents sent to or received from participant regarding an adverse benefits determination for Lipitor)
- No. 79 [19] (documents concerning false claims for reimbursement)
- No. 80 [20] (documents identifying each instance where Fund required participant to seek second opinion regarding Lipitor)
- No. 81 [21] (utilization analyses regarding pharmacy benefit coverage)
- No. 82 [22] (documents sent or received by Fund regarding any Lipitor prescription filled by participant)

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<sup>6</sup> Bracketed numbers refer to the corresponding requests in Pfizer's Second Request for Production to the Illinois Funds.

- No. 84 [24] (documents discussing overuse/over-prescription of Lipitor)
- No. 62 (audits of Fund plans)
- No. 85 (documents sufficient to identify the physical location of documents containing claim info regarding Lipitor)

In addition, despite their commitment to provide responses to the following requests, the majority of the Funds have not produced any responsive documents, and the others have produced only incomplete responses:

- No. 1 (documents referenced in the Complaint and Amended Complaint)
- No. 2 (documents received from Pfizer or any PBM regarding Lipitor)
- No. 3 (documents regarding Lipitor provided by Fund to participants)
- No. 4 (documents provided by anyone else to participants regarding Lipitor)
- No. 8 (documents reflecting any payment for Lipitor between January 1, 2002 and June 6, 2006)
- No. 11 (contracts between Fund and any PBM for the last ten years)
- No. 12 (contracts between Fund and any other entity involving the payment/reimbursement for Lipitor)
- No. 15 (documents regarding Lipitor reimbursement or payment practices and procedures)
- No. 16 (documents regarding PBM practices/procedures with respect to Lipitor)
- No. 21 (documents provided to participants or physicians by Fund regarding reimbursement/payment for Lipitor)
- No. 27 (guidelines or procedures used to evaluate claims for reimbursement)
- No. 38 (documents reflecting agreements between Fund and employer regarding pharmacy benefits)
- No. 48 (copies of agreements with third party administrators)
- No. 51 (documents specifying medicines on Fund formulary for past four years)
- No. 52 (documents reflecting restrictions on any formulary medicine for past four years)
- No. 53 (contracts between Fund and any entity providing assistance or consulting with regard to its PBM)
- No. 55 (documents reflecting all payments made for Lipitor after lawsuit commenced)
- No. 63 [3] (trust agreement creating the Fund)

- No. 65 (documents from PBM identifying prescription medicines added to/removed from formulary)
- No. 73 [13] (guidelines or procedures regarding claim review process)
- No. 74 [14] (documents showing total amount reimbursed by Fund for Lipitor prescriptions filled at retail pharmacies)
- No. 75 [15] (documents showing total amount reimbursed by Fund for Lipitor prescriptions filled by mail order)

Plaintiffs have offered no justification for their failure to produce the foregoing categories of admittedly discoverable documents. Having taken months purportedly to collect them, and having already staved off one motion to compel by apologizing and promising to promptly rectify their discovery deficiencies, the Funds should immediately produce all responsive documents. *See Eley*, 2005 U.S. Dist. LEXIS 30476, at \*6.<sup>7</sup>

## II. PLAINTIFFS MUST PRODUCE UNREDACTED PRESCRIPTION RECORDS

In its interrogatories and requests for documents, Pfizer has requested basic information about, and documentation of, the allegedly improper “off-label” prescriptions for which Plaintiffs seek billions of dollars from Pfizer, and on which they now purport to base their modified “price inflation” theory of damages, including the identities of participants who filled Lipitor prescriptions during the relevant time period and the identities of participants whom Plaintiffs allege were prescribed Lipitor for an off-label purpose as defined in the Amended Complaint. *See, e.g.*, Ex. A, Nos. 5, 6, 36. This Court has agreed that this information is

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<sup>7</sup> Plaintiffs have also improperly *refused* to provide documents in response to the following requests: Nos. 5-6 (documents sufficient to identify each participant who purchased/was prescribed Lipitor for off-label purpose (Plaintiffs agreed only to provide redacted information)); No. 36 (name and address of each participant who has filled a Lipitor prescription (Plaintiffs agreed only to provide redacted information)); No. 49 (documents provided by Fund to participants regarding healthcare and pharmacy benefits); No. 69 [9] (documents identifying each employer who has provided funding to the Fund); No. 70 [10] (collective bargaining agreements for each employer identified); No. 78 [18] (annual reports filed by Fund with government agencies); and No. 86 [26] (documents containing passwords to access Fund’s website).

“clearly relevant” and discoverable. *See* 6/13/07 Tr. (“Tr.”) at 31. Indeed, the Court has emphasized that “*the names are the start*” of the prescription information Plaintiffs must provide in response to Pfizer’s outstanding requests. Tr. at 34 (emphasis added); *id.* at 42 (directing Plaintiffs to start with one Fund and provide “the names” and “the prescriptions that are allegedly for the improper off-label usage”); 6/14/07 Minute Order; 8/28/07 Minute Order (directing each of the other Funds to provide the same). Moreover, Pfizer is entitled to learn the volume of prescriptions filled by participants, costs paid, and other demographic information.

In addition, Plaintiffs’ counsel has conceded not only that the parties’ existing protective order ensures the confidentiality of participant information, but that providing participant names would be “administratively” simple:

MR. GRYGIEL: . . . I mean truly, your Honor, producing the names is, you know, it’s administratively, as you know from the documents that Mr. Cheffo was describing, a matter of just unredacting on a live e-mail basis or a live computer basis the names. We can do that. I just needed permission to do it and so far I think two plans have said go ahead, give them the names, we’ve got a protective order, that’s okay.

Tr. at 34. Indeed, the parties’ protective order [D.E. 48] was negotiated specifically to permit the disclosure of participant information. To date, however, over a year after Pfizer first requested the relevant participant names and other prescription information from the original Funds, and over two months after this Court ruled that Pfizer is entitled to obtain it, only seven of the twelve Funds have produced *any* information about Lipitor prescriptions filled by their participants, and four of the seven have redacted participant names and other relevant data, such as dates of birth. Specifically, Plaintiffs New York City Police Sergeants Benevolent Association Health & Welfare Funds, the Welfare Fund of Teamsters Local Union 863, Southern Illinois Laborers’ and Employers Health and Welfare Fund, and Midwestern Teamsters Health and Welfare Fund have

refused to provide unredacted Lipitor prescription claim records.<sup>8</sup> Moreover, the following five Funds have not provided *any* prescription information nor indicated that they will produce unredacted information: Cleveland Bakers and Teamsters Health and Welfare Fund, Fire & Police Retiree Health Care Fund, San Antonio, Laborers' District Council Building and Construction Health and Welfare Fund, Laborers' District Council Heavy and Highway Utility Health and Welfare Fund, and Sidney Hillman Health Center of Rochester.<sup>9</sup>

Pfizer has repeatedly objected to Plaintiffs' redactions and requested that they produce unredacted Lipitor prescription records containing, at a minimum, participants' names, the prescribing physicians, and other medicines that the participants had taken.<sup>10</sup> Plaintiffs' counsel has not disputed that Pfizer is entitled to relevant participant names, but has indicated that at least four Funds nevertheless continue to refuse to "authorize" their disclosure. As noted, this Court has already found that position untenable. *See* Tr. at 42 ("We want the names, we want the prescriptions that are allegedly for the improper off-label usage. That's what we want."). Having commenced this litigation, Plaintiffs do not have the option of simply refusing to ignore the Court's orders or Pfizer's discovery requests.

Accordingly, Pfizer requests that this Court compel the four Funds that have provided improperly redacted prescription information, and the five Funds that have not provided *any*

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<sup>8</sup> Although Plaintiffs also originally produced redacted records for two other Funds, Electrical Workers Benefit Trust Fund and Plumbers & Pipefitters, they have since provided unredacted versions.

<sup>9</sup> Judge Darrah has separately directed Plaintiff Sidney Hillman to respond to all outstanding discovery, in connection with its motion to voluntarily dismiss its claims with prejudice. *See* 8/16/07 Minute Order [D.E. 108]. To date, Sidney Hillman has produced only 84 pages.

<sup>10</sup> *See, e.g.*, Ex. B, 6/5/07 e-mail from M. Cheffo to S. Grygiel; Ex. C, 7/18/07 e-mail from M. Cheffo to S. Grygiel; Ex. D, 7/25/07 letter from M. Cheffo to S. Grygiel.

prescription information, to promptly provide unredacted records, including participant names, dates of prescription, prescriber details, and concomitant medicines.

### **III. PLAINTIFFS MUST PROVIDE INFORMATION ABOUT THE CONFIDENTIAL AND INTERNAL PFIZER DOCUMENTS THEY HAVE OBTAINED AND REFERENCED IN THEIR PLEADINGS**

Plaintiffs have improperly objected and refused to respond to Pfizer's interrogatory requesting information about how and from whom they obtained over 2,200 pages, along with audio and video cassette tapes and CDs, of internal, confidential, proprietary, and apparently misappropriated, Pfizer materials that they have referenced in their pleadings and produced to Pfizer during discovery. Specifically, on February 14, 2007, after eight months of delay, Plaintiffs *collectively* produced to Pfizer two boxes containing over 2,260 pages, two audio cassettes, two video cassettes, and three CDS (PLCONS00001-002269). The production includes numerous non-public Pfizer documents and items, including Lipitor-related internal training and presentation materials. Many of the documents indicate on their face that they are not to be distributed or used outside of Pfizer. Yet all twelve Funds have claimed, through their collective production, to have possession of the identical set of materials, and have specifically referenced at least two of the presentations in their Complaints. *See* Am. Compl. ¶¶ 57, 88-89; Second Am. Compl. ¶¶ 107, 121-22.

On May 18, 2007, Pfizer served a narrow, straightforward interrogatory asking one of the Funds to:

identify the individual or individuals who provided to you documents and other items bates stamped as PLCONS 000001-002269, and describe the circumstances under which these documents and materials were given or shown to you.

The Fund, New York City Police Sergeants Benevolent Association Health & Welfare Funds ("NY SBA"), refused to provide a substantive response consistent with the Federal Rules and this Court's admonitions, and instead asserted:

In addition to the foregoing general objections, Plaintiff objects to this interrogatory because the information requested is protected by the work product doctrine, and was developed for or in anticipation of litigation. Plaintiff further objects to this interrogatory because it calls for information that is neither relevant nor reasonably calculated to lead to the discovery of relevant evidence.

Ex. E, NY SBA's Responses and Objections to Defendant Pfizer Inc's Fourth Interrogatories, No.

1. In letters to Plaintiffs' counsel on June 20 and July 11, 2007, Pfizer objected to NY SBA's response and asked that it supplement it with the requested information.<sup>11</sup> Plaintiffs have refused to do so.

Plaintiffs cannot support their position. *Factual* information about their acquisition and possession of Pfizer's internal and proprietary documents and other materials that Plaintiffs have produced – and referenced in support of their claims – including when, how, and from whom they received them, is plainly relevant and discoverable. Indeed, the person(s) who provided the materials to Plaintiffs are likely material witnesses in this litigation. Moreover, Pfizer is entitled to determine whether its confidential and proprietary documents were improperly obtained or distributed, when Plaintiffs received them, who saw and relied on them (if anyone), and how, if at all, they were disseminated to physicians and Fund participants.

Plaintiffs certainly cannot justify their withholding of this information under the work product doctrine. “The work product privilege protects ‘documents and tangible things otherwise discoverable . . . prepared in anticipation of litigation or for trial by or for another party or by or for that other party’s representative . . . .’” *Patterson v. Burge*, No. 03 C 4433, 2007 U.S. Dist. LEXIS 33102, at \*8-9 (N.D. Ill. May 4, 2007) (Soat Brown, J.) (quoting Fed. R. Civ. P. 26(b)(3)); *accord Am. Floral Servs., Inc. v. Florists’ Transworld Delivery Assoc.*, 107

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<sup>11</sup> See Ex. F, 6/20/07 letter from M. Cheffo to S. Grygiel; Ex. G, 7/11/07 letter from M. Cheffo to S. Grygiel at 3.

F.R.D. 258, 260 (N.D. Ill. 1985). By contrast, as this Court explained in *Patterson*, “factual information that [a plaintiff] has about [its] case . . . is not protected work product.” 2007 U.S. Dist. LEXIS 33102, at \*9 (compelling plaintiff to “testify as to any factual information of which he is aware regarding [his] case, whether or not that information was obtained in the course of his investigations” of his own allegations). Here, the requested information – how, when, and from whom Plaintiffs obtained the documents – constitutes plainly discoverable factual information about Plaintiffs’ case and Pfizer’s internal documents, not protected attorney work product. Further, “the identity of witnesses having knowledge of relevant facts” – here, the person(s) from whom Plaintiffs obtained the materials – is also “discoverable information.” *Am. Floral Servs., Inc.*, 107 F.R.D. at 260. Courts have also emphasized that “[t]he attorney work product privilege *does not* preclude the disclosure of *facts* or the identity of witnesses or documents simply because their existence was discovered by counsel.” *Clark Equip. Co. v. Lift Parts Mfg. Co.*, No. 82 C 4585, 1985 U.S. Dist. LEXIS 15457, at \*19 (N.D. Ill. Sept. 30, 1985) (emphasis in original); *see also id.* (“A party clearly cannot refuse to answer interrogatories on the ground that the information sought is solely within the knowledge of his attorney.”).

Accordingly, Pfizer is entitled to request and obtain factual information concerning Plaintiffs’ acquisition of internal Pfizer documents that are referenced in their Complaints, and Plaintiffs should be compelled to provide it.

#### **IV. PLAINTIFFS MUST PRODUCE DOCUMENTS RELATING TO THEIR IDENTIFICATION OF ANY IMPROPER OFF-LABEL PRESCRIPTIONS**

In addition to participant names, Pfizer has requested documents relating to Plaintiffs’ evaluation of any allegedly improper off-label Lipitor prescriptions it identifies in response to Pfizer’s requests and this Court’s orders. Although Plaintiffs originally refused to produce much of this information, they changed their position after Pfizer moved to compel, and on June 6,

2007, filed supplemented and amended responses in which they agreed to produce it. *See, e.g.*, Ex. A, Nos. 23, 24, 35, 45, 47, 60, 67, 68, 82; *supra* Part I. Now, nearly three months later, after side-stepping Pfizer's motions to compel, Plaintiffs have not produced any of this information, apart from the medical records they obtained in connection with the few Plumbers and Pipefitters prescriptions they have identified as "off-label." Plaintiffs have otherwise reverted to their original position of refusing to provide the other requested records, including the correspondence and analysis on which they have relied in identifying the prescriptions. Plaintiffs cannot defend their refusal to disclose documents and information on which they purport to base their identification of what this Court has held constitutes evidence of their alleged damages. Accordingly, this Court should compel them to do so.

### **CONCLUSION**

For the foregoing reasons, Pfizer respectfully requests that this Court order Plaintiffs to produce (1) substantive responses to Pfizer's outstanding requests for documents; (2) unredacted documents containing the identities of participants who filled Lipitor prescriptions; (3) a response to Pfizer's interrogatory about the circumstances by which Plaintiffs obtained internal Pfizer documents; and (4) records relating to Plaintiffs' identification of improper off-label Lipitor prescriptions, and grant any further relief that the Court deems just and proper.

DATED: September 7, 2007

Respectfully submitted,

**PFIZER INC**

By its attorneys,

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### **CERTIFICATE OF SERVICE**

I, Andrew J. Jarzyna, an attorney, certify that on this 7th day of September, 2007, one true and correct copy of the foregoing Motion to Compel was served through this Court's electronic filing system upon the following counsel for Plaintiffs: George S. Bellas, gsb@cliffordlaw.com; Robert A. Clifford, rac@cliffordlaw.com; Sidney S. Liebesman, sliebesman@gelaw.com; Patrick J. O'Hara, patrick@cavanagh-ohara.com; and Thomas K Prindable, tkp@cliffordlaw.com.

/s/Andrew J. Jarzyna  
Andrew J. Jarzyna

# **EXHIBIT T**

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

SOUTHERN ILLINOIS LABORERS'	)	
AND EMPLOYERS HEALTH AND	)	
WELFARE FUND; NECA-IBEW	)	
WELFARE TRUST FUND;	)	CIVIL ACTION No. 06-CV-1818
MIDWESTERN TEAMSTERS HEALTH	)	
AND WELFARE FUND; THE	)	
WELFARE FUND OF TEAMSTERS	)	JUDGE JOHN W. DARRAH
LOCAL UNION 863; PLUMBERS AND	)	
PIPEFITTERS LOCAL UNION 630	)	MAGISTRATE JUDGE
WELFARE TRUST FUND;	)	GERALDINE SOAT BROWN
CLEVELAND BAKERS AND	)	
TEAMSTERS HEALTH AND WELFARE	)	
FUND; ELECTRICAL WORKERS	)	
BENEFIT TRUST FUND; FIRE &	)	
POLICE RETIREE HEALTH CARE	)	
FUND, SAN ANTONIO; LABORERS'	)	
DISTRICT COUNCIL BUILDING AND	)	
CONSTRUCTION HEALTH AND	)	
WELFARE FUND; LABORERS'	)	
DISTRICT COUNCIL HEAVY AND	)	
HIGHWAY UTILITY HEALTH AND	)	
WELFARE FUND; NEW YORK CITY	)	
POLICE SERGEANTS BENEVOLENT	)	
ASSOCIATION HEALTH & WELFARE	)	
FUNDS; and SIDNEY HILLMAN	)	
HEALTH CENTER OF ROCHESTER,	)	
individually, and on behalf of all others	)	
similarly situated,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
PFIZER INC.,	)	
	)	
Defendant.	)	

**PLAINTIFFS' OPPOSITION TO PFIZER'S MOTION TO COMPEL PLAINTIFFS TO  
PROVIDE DOCUMENTS, UNREDACTED CLAIMS RECORDS, AND RESPONSES  
CONCERNING PFIZER'S PROPRIETARY MATERIALS**

### INTRODUCTION

Plaintiffs hereby respond to Defendant Pfizer, Inc. ("Pfizer")'s Motion to Compel certain documents, unredacted claims records, and an answer to an interrogatory regarding the source of certain information in Plaintiffs' complaint. Specifically, Pfizer asks the Court to compel Plaintiffs to produce four categories of information and documents: (1) documents responsive to Pfizer's written requests for production of documents that relate to Plaintiffs' no longer operative complaint and are irrelevant to Plaintiffs' Second Amended Complaint ("SAC"); (2) unredacted documents concerning plan participants who were prescribed Lipitor; (3) a response to Pfizer's interrogatory concerning the source of some of Plaintiffs' information; and (4) documents relating to Plaintiffs' identification of off-label Lipitor prescriptions. Pfizer's motion should be denied because much of the information Pfizer seeks is outside of Plaintiffs' care, custody and control, and, further, is irrelevant to the SAC, which the Court permitted over Pfizer's strenuous objection. To the extent that any of the information Pfizer seeks is marginally relevant, the burden of production for Plaintiffs outweighs any probative value.

Plaintiffs are third-party payor funds that pay medical bills for plan participants who receive Lipitor prescriptions. Plaintiffs are not document repositories. They do not have access to much of the information Pfizer seeks to compel. Plaintiffs should not be compelled to locate and produce documents outside of their care, custody or control, such as documents regarding whether a particular prescription was written for an off-label use. To the degree that off-label prescriptions factor into Plaintiffs' claims and damages, Plaintiffs will put forth expert economic and statistical evidence using an approach accepted by other courts in similar situations. Pfizer can challenge Plaintiffs' claims with similar evidence, available to Pfizer without the burdensome discovery it seeks and that is extremely difficult, if not impossible, for Plaintiffs to

provide. Finally, Plaintiffs should not be compelled to reveal information about their legal strategy by producing names or information about Plaintiffs' sources at this stage of the case.

### **FACTS**

Plaintiffs' document production thus far has been in response to this Court's prior discovery orders that Plaintiffs produce documents in support of their former theory of damages. More specifically, those orders compelled Plaintiffs to identify, locate, obtain and produce information, including personal medical records, of thousands of non-party participants in the Plaintiff Funds. This information was not within the Plaintiffs' care, custody or control. However, the Court compelled production based on the information's direct relevance to the Plaintiffs' damages claim. The compelled information is still not within the Plaintiffs' care, custody or control. And now, with the SAC's different damages theory, the compelled information is irrelevant. Any remote relevance is completely outweighed by the undue burdens in identifying, locating, obtaining, examining and producing such information.

Accordingly, on September 10, 2007, Plaintiffs moved to modify ("Plaintiffs' Motion to Modify") the Court's prior discovery orders. That motion, incorporated herein by reference, explains the enormous burden the Florida Fund faced in complying with this Court's June 16, 2007 Order to produce the medical records of its beneficiaries. Plaintiffs had to locate the doctors' addresses by web-based searches and other investigations, and were often unable to locate doctors having responsive medical records of beneficiaries. Plaintiffs' attempts were further complicated because many doctors who had beneficiary medical records refused to turn them over without patient consent, citing HIPAA concerns and state laws protecting patient privacy. Plaintiffs have produced documents through this time-consuming and administratively burdensome work. These documents are outside of Plaintiffs care, custody and control, and any

further obligation to obtain documents from other physicians and plan representatives would increase Plaintiffs' burden exponentially.

### ARGUMENT

#### **A. PFIZER'S PRIOR DOCUMENT REQUESTS SEEK INFORMATION NOT WITHIN THE PLAINTIFFS' CARE, CUSTODY OR CONTROL.**

The Court's existing discovery orders compel production of information, including personal medical records, of third-parties, non-litigant Fund participants. Fundamentally important, the Plaintiffs do not keep medical records of beneficiaries in their care or custody in the regular course of the Plaintiffs' business. Nor do the Plaintiffs have "control" over them. Fed. R. Civ. P. 34(a). "Control has been defined to include 'the legal right to obtain the documents requested upon demand'" and "is to be liberally construed." *Modern Eng'g. Inc. v. Peterson*, No. 07-CV-1055, 2007 WL 2680563, at \* 3 (C.D. Ill. July 16, 2007) (refusing to compel production of documents that "belong" to defendant's new employer). The Florida Fund was able to obtain some medical records without executed releases by the Fund's participants, by explaining to recalcitrant doctors and their office administrators that the Court's discovery orders (45 C.F.R. § 164.512(e)(1)(i)) and the HIPAA-compliant Confidentiality Order (45 C.F.R. §§ 164.512(e)(1)(ii)(B), 164.512(e)(1)(v)(A)(B)) substituted for an executed patient release.

But numerous doctors, citing HIPAA, simply would not produce records without a release, citing HIPAA concerns and the customary practice of requiring a patient-executed release — "no matter what." Counsel for certain doctors and medical groups also argued, correctly, that the Court's orders and the Confidentiality Order did not end the inquiry. Rather, HIPAA pre-emption notwithstanding, to the extent state disclosure laws are "contrary" to HIPAA, those more restrictive state laws control. *See, e.g., National Abortion Federation v. Ashcroft*, No. 04 C 55, 2004 WL 292079, \* 2 (N.D. Ill. Feb. 6, 2004) (Illinois's disclosure laws

more restrictive than, and therefore contrary to, HIPAA, so Illinois's more restrictive rule controlled). State laws are "contrary" to HIPAA where state law would prohibit disclosure of personal medical information and HIPAA would permit the disclosure. *Id.* ("A contrary state health information privacy law will not be preempted by a HIPAA regulation if the state law is 'more stringent' than HIPAA's requirements." (citing 45 C.F.R. § 160.203(b), *U.S. ex rel. Stewart v. Louisiana Clinic*, No. 99-1767, 2002 WL 31819130, \*3 (E.D. La. 2002)). Even liberally construing Fed. R. Civ. P. 34(a)'s "control" trigger, for many Funds "control" either does not exist or is, at best, unclear.

Dispositively, in any event, beyond the lack of care, custody or control of such records, the process of obtaining medical records from doctors is more than merely burdensome. *See Cohn v. Taco Bell Corp.*, No. 92 C 5852, 1993 WL 451463, at \*4 (N.D. Ill. Nov. 1, 1993) (holding plaintiff did not have to produce documents where the burden of gathering "records [was] quite large, in relation to the small value that they have in th[e] litigation"), *aff'd* 1994 WL 383975 (N.D. Ill. Jul. 20, 1994). Described in detail in Plaintiffs' Motion to Modify, Plaintiff Plumbers & Pipefitters Local Union 630 Welfare Trust faced enormous burdens in complying with this Court's June 16, 2007 Order to produce the medical records of its beneficiaries. That burden, imposed under a different complaint with a different damages claim, will be multiplied tenfold unless the Court denies Pfizer's motion to compel.

Many participants have more than one prescribing doctor. Once having found the doctors' addresses – involving time-consuming research and telephone calls in many cases – Plaintiffs then must secure medical information release authorization forms from all of the Lipitor-taking Fund participants, and send those to the doctors. Then, of course, as Plaintiffs experienced in the Florida Fund test case, Plaintiffs must chase down records that have gone into

storage, records disappeared from doctors' offices that have moved or closed, negotiate the prices for file duplication and mailing, and do many other such tasks in seeking to get the actual records. Once the records are finally obtained, Plaintiffs must send them to a doctor, a dyslipidemia expert, for review and identification of off-label prescriptions by review of records against the template of the established guidelines of the NCEP ATP III.

This hugely time-consuming, administratively burdensome process is, essentially, unworkable. Absent denial of Pfizer's motion, Plaintiffs would now have to perform this process to obtain information of no, or, at best, marginal, relevance. .

**B. PFIZER'S PRIOR DOCUMENT REQUESTS ARE LARGELY IRRELEVANT TO THE ISSUES RAISED IN THE SAC AND IMPOSE UNDUE BURDEN**

The requested discovery must be relevant. A "proponent of a motion to compel discovery . . . bears the initial burden of proving that the information sought is relevant." *West v. Miller*, No. 05C4977, 2006 WL 2349988, at \*2 (N.D. Ill. Aug. 11, 2006) (internal quotes omitted). A motion to compel will be denied if the moving party cannot meet this initial burden. *See id.* ("[F]ailure to make even a colorable initial showing as to relevance can doom a motion to compel."). Second, if the motion to compel seeks relevant information, courts will deny the motion where the request for information is "unduly burdensome." *Miller v. Pinkston*, No. 96 C 4675, 1999 WL 691827, at \*3 (N.D. Ill. Aug. 26, 1999). *See also Dodson v. Lowe's Home Center, Inc.*, No. 05-4068-GPM, 2006 WL 1877040, at \*3 (S.D. Ill. Jul. 6, 2006) (holding that defendants need not respond to interrogatories that are "overly broad, unduly burdensome, [and] vague").

**1. Pfizer Seeks Irrelevant Information**

Much of the information Pfizer seeks to compel is no longer relevant. The complaint under which Pfizer propounded its discovery is no longer operative. Measuring the damages the

SAC alleges does not require detailed patient-specific medical information. Unlike the preceding Complaint, the SAC does not allege that individual Plaintiffs were duped into paying for specific off-label prescriptions because of a fraudulent marketing campaign. Rather, the SAC alleges that Pfizer's off-label or fraudulent marketing drove demand up and increased the price of Lipitor. See, e.g., SAC at ¶ 30 ("Further, Pfizer expanded the market and demand for Lipitor, creating the artificially increased prices for Lipitor, not only by illegally promoting the off-label use of the drug, but also by concealing or minimizing the health risks associated with statin use, and by wrongfully promoting Lipitor as superior to and safer than other statin alternatives.").

Plaintiffs' damages now require calculations of the total amount of Lipitor prescriptions for which Plaintiffs paid; the price of the prescriptions; and the prices that would have been obtained had Pfizer not engaged in its wrongful overpromotion of Lipitor. These calculations will not require painstaking investigation of individual medical records and prescriptions. Plaintiffs will compute these damages using expert economic testimony and statistical analysis based on Pfizer's own documents; Plaintiffs' records; and commercially available data. Plaintiffs' Motion to Modify Discovery, filed on September 6, 2007, explains that courts have accepted this type of statistic-based damage calculation in similar medical and pharmaceutical litigation. See, e.g., *In re Neurontin Mktg. and Sale Practices Litig.*, No. 04-10981, 2007 WL 2437954 at \*20 (D. Mass. Aug. 29, 2007) (approving as a "widely-used statistical tool" a "time-series regression analysis" used by plaintiffs' expert to "calculate the total number of off-label prescriptions that were caused by defendants' off-label marketing activities"); *Klay v. Humana, Inc.*, 382 F.3d 1241, 1259-1260 (11th Cir. 2004) (certifying class of HMO subscribers in RICO action where damage calculations can be computed "according to some formula, statistical analysis, or other easy or essentially mechanical methods").

Much of the information Pfizer seeks is irrelevant to the SAC's allegations. For example, Pfizer seeks documents identifying "any physician who prescribed Lipitor to a participant for an off label purpose" (Mot. to Compel at 5, request no. 7); "the LDL level of each participant who received an off-label Lipitor prescription" (*id.* at 6, request no. 23); "the ten-year cardiac risk profile for same" (*id.* at request 24); "each participant denied reimbursement for Lipitor" (*id.* at request 26); "the name of each physician who has written a Lipitor prescription for any participant during the relevant time period" (*id.* at request 37); "any beneficial health effects received by off-label Lipitor patients" (*id.* at request 43); "documents from physicians regarding the use of Lipitor by participants" (*id.* at request 45); "a copy of each [off-label] Lipitor prescription" (*id.* at 7, request no. 46); "the name and dose of any medicine taken concomitantly with Lipitor by [an] off-label participant" (*id.* at 7, request no. 66); "each participant who filled [a] prescription for another statin before Lipitor" (*id.* at 7, request no. 67); "off-label participants' LDL, HDL and triglyceride levels" (*id.* at 7, request no. 68); and "each instance where Fund required participant to seek second opinion regarding Lipitor" (*id.* at 7, request no. 80).

## **2. Pfizer's Requests Are Unduly Burdensome Because Pfizer Seeks Information Plaintiffs Do Not Possess Or Control**

To the extent any of the information Pfizer seeks is relevant to the issues raised in the SAC, the heavy burden of finding and producing this information outweighs any probative value of the information. Pfizer's Motion to Compel lists 89 discovery requests (including 18 purportedly duplicative of other requests) that Pfizer seeks to obtain from 12 separate Plaintiff funds. The sheer volume of these requests demonstrates Pfizer's true intention – to overburden Plaintiffs with discovery requests that are not necessary to establish or defend against Plaintiffs' case. To date, Pfizer has made over 200 documents requests to all Plaintiffs, including 39 requests to all Plaintiffs after Plaintiffs filed the SAC. Plaintiffs, third-party payor funds, simply

do not possess or control much of the individual physician and patient information Pfizer seeks. This Court has previously acknowledged the extreme burden Plaintiffs face in obtaining and producing this information when it initially required Plaintiffs only to obtain such information from one "test case" fund. Now that Plaintiffs' have amended their theory - expressly to narrow the scope of relevant information - Pfizer insists on pursuing discovery as if Plaintiffs' motion to amend their complaint had been denied.

Further, Plaintiffs have produced fund-specific data that, coupled with statistical analysis of Pfizer and industry data, provides Plaintiffs with standing, permits a proper damages calculation, and permits Pfizer to test Plaintiffs' claims. Plaintiffs have not, as Pfizer contends "not honored their commitment" and "proceeded as if Pfizer's discovery requests do not exist." (Mot. to Compel at 4).

**C. THE INFORMATION PLAINTIFFS REDACTED FROM INDIVIDUAL PRESCRIPTION RECORDS IS NOT DISCOVERABLE**

Pfizer seeks the identities of individual fund participants primarily to harass Plaintiffs in an attempt to short circuit this litigation. Defendant Pfizer has and will use these names to seek discovery of private medical data.<sup>1</sup> Understandably, these individual beneficiaries are reluctant to share these intimate details with Pfizer. Granting the Motion To Compel would place Plaintiffs in an untenable double bind: produce intimate details of beneficiaries' medical records that are largely if not completely irrelevant to the SAC, or forgo any attempt to recover damages due to Pfizer's fraudulent marketing campaign. In light of the difficulties the Test Case

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<sup>1</sup> After Plaintiff Plumbers and Pipefitters Local Union No. 630 Welfare Fund identified patients who took Lipitor for off-label purposes, Pfizer sent these beneficiaries a list of 10 substantially overbroad interrogatories, seeking, *inter alia*, all medications prescribed to the patient in the last 10 years (Req. No. 8); parents' and siblings' medical history (Req. No. 6); and all medical records, reports, blood test or lab results the beneficiary received from any physician, hospital or other health care provider within the last 10 years (Req. No. 1).

highlighted, many Plaintiffs are loathe to subject their beneficiaries to similar harassing litigation tactics.

Beneficiary names have, at most, limited relevance. Divulging these names would be an unwarranted intrusion on the privacy of beneficiaries. *See Trading Technologies Intern., Inc. v. eSpeed, Inc.*, 2006 WL 3541933, at \*1 (“Where . . . confidential information is at stake, we must balance the relevance of the discovery sought, the requesting party’s need, and the potential hardship to the party subject to the subpoena.”) (internal citations and quotations omitted). The Court should not allow discovery where it burdens non-parties, and for no particularly relevant purpose. *See id.* (“And although the rules contemplate discovery of non-parties, we can consider the fact that Brucato and Catus are not parties to this litigation in weighing burdens.”) (internal citations omitted). As set forth below: (1) patient names have limited relevance; (2) Pfizer has a limited need for patient names; and (3) producing patient names would be unduly burdensome.

*First*, because Plaintiffs will rely primarily on statistical data and expert testimony to prove that Pfizer’s fraudulent marketing campaign improperly increased demand for Lipitor and thereby increased Lipitor’s price, the names of individual beneficiaries have limited relevance to this case. Companies such as IMS Health and Verispan obtain detailed information on patients who were prescribed Lipitor, including their LDL levels and other risk factors of heart disease and do careful projections from that data. Pfizer itself buys that data from both companies, using it, among other purposes, to determine how and where to spend marketing dollars, and which sales representatives have earned bonuses. Compared to this highly refined data, derived from thousands of patients, medical records from fund beneficiaries has limited probative value.

Under Plaintiffs' price inflation theory, whether individual beneficiaries received Lipitor for off-label use is wholly irrelevant for purposes of calculating damages. To calculate damages, Plaintiffs merely need to subtract the amount paid for Lipitor by the amount that Plaintiffs' experts determine the price of Lipitor was inflated.<sup>2</sup> For purposes of calculating damages, therefore, it is not necessary to determine whether individual fund members were prescribed Lipitor because of Pfizer's off-label marketing campaign.

*Second*, Pfizer has little need for patient names beyond harassing Plaintiffs' beneficiaries. *See Trading Technologies*, 2006 WL 3541933, at \*2 (refusing to grant discovery where "the possibility for [harassment] . . . is readily apparent."). To dispute Plaintiffs' statistical analysis of data, Pfizer can rely on its own experts. In fact, Pfizer has not convincingly explained how it intends to use individual patient names to rebut Plaintiffs' plan to use statistical data.<sup>3</sup>

*Third*, producing beneficiary names would be unduly burdensome as it would subject beneficiaries' private medical data to scrutiny by Pfizer. In *Johnson by Johnson v. Thompson*, 971 F.2d 1487, 1497 (10th Cir. 1992), the court upheld a district court decision not to compel physician-defendants to produce the names of patients, which would enable plaintiff to seek discovery from them. In that case, plaintiff, who claimed that his doctors did not recommend aggressive treatment for his son's spina bifida because of his socio-economic status, sought to

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<sup>2</sup> To the extent that Pfizer asked for the total amount each Plaintiff spend on Lipitor, Plaintiffs agree to produce such information.

<sup>3</sup> Pfizer's argument that the protective order somehow changes Pfizer's burden to show relevance and need (Def. Br. at 10) is wrong as a matter of law. *See Micro Motion, Inc. v. Kane Steel Co., Inc.*, 894 F.2d 1318, 1325 (Fed. Cir. 1990) ("As an initial matter, we reject Micro Motion's argument that the protective order, entered by the court here, obviates K-Flow's objections to discovery. The protective order is not a substitute for establishing relevance or need.").

impeach the doctors who stated that they made no treatment recommendations, but generally presented patients with a menu of options on how to treat spina bifida. The court held that patient names would lead plaintiff to relevant information, however, patients and their families were "entitled to privacy and confidentiality" with respect to their medical records and communications with their doctors. *See id.* Similarly here, revealing beneficiary names will expose them to an unwarranted intrusion on their privacy by Pfizer.

Pfizer, however, erroneously states that "Plaintiffs' counsel has not disputed that Pfizer is entitled to relevant participant names." Mot. To Compel at 11. At the August 18, 2007 hearing, Plaintiffs, however, made clear that it sought to file the SAC for the express purpose of streamlining discovery to make patient names and medical records irrelevant to proving Plaintiffs' claims. *See* 8/28/2007 Tr. at 25-26. Plaintiffs reiterated the point at the September 4, 2007 hearing before this Court:

I took the position in this courtroom last week and I took it downstairs today that our position and our reason for doing this, as I was very candid with the court to say, was because the individualized discovery that is required is unduly burdensome for the plaintiffs to prove their case, and as we have seen in other cases, for example, in Zyprexa and, for example, in the class certification opinion in Neurontin, we want to do this on an aggregate basis.

9/4/07 Tr. at 5 (Stephen G. Grygiel). Thus, Plaintiffs have made clear that they have amended their complaint to streamline their theory of damages to make individualized discovery unnecessary.

**D. PLAINTIFFS' SHOULD NOT BE COMPELLED TO REVEAL THE SOURCE OF CERTAIN INFORMATION.**

Pfizer contends that Plaintiffs must provide information about certain Pfizer documents referenced in Plaintiffs' pleadings. Specifically, Pfizer seeks to compel Plaintiffs to answer an interrogatory by identifying the individual or individuals who provided Plaintiffs with these documents and describing the circumstances under which the documents were provided. Mot. to

Compel at 12. Plaintiffs, however, should not be required to identify individuals interviewed as part of a pre-suit investigation.

Courts have held that a party cannot be compelled to disclose the identity of witnesses interviewed in pre-suit investigation because such disclosure reveals attorney mental impressions and trial strategy. See *In re MTI Tech. Corp. Sec. Litig. II*, No. 00-0745-DOC, 2002 WL 32344347 at \* 3 (C.D. Cal. Jun. 13, 2002) ("if the identity of interviewed witnesses is disclosed, the opposing counsel can infer which witnesses counsel considers important, revealing mental impressions and trial strategy."); *In re Ashworth, Inc. Sec. Litig.*, 213 F.R.D. 385, 389 (S.D. Cal. 2002) (identification of witnesses in an interrogatory "would necessarily reveal counsel's opinions regarding the relative importance of these witnesses, the highlights of their testimony/factual knowledge, and would link any future statements by the witnesses with [p]laintiff's counsel's legal theories and conclusions as outlined in the complaint") citing *In re MTI*, 2002 WL 32344347 at \*4. Courts have acknowledged the strong public policy interest in protecting the identity of these interviewees. *In re Ashworth*, 213 F.R.D. 389 ("there is a legitimate policy concern that militates against requiring disclosure even though the whistleblower privilege is not available in a private suit") quoting *In re MTI*, 2002 WL 32344347 at \*5.

In *In re MTI*, the district court reversed the magistrate judge's order compelling plaintiffs to identify the names of former MTI employees plaintiffs had interviewed in drafting their complaint. The court explained that while the identity of fact witnesses is discoverable, the identity of witnesses interviewed by opposing counsel is protected by the work-product doctrine:

Although the identity and location of witnesses that may have knowledge of any discoverable matter is not protected, the identity of witnesses interviewed by opposing counsel is protected. *Massachusetts v. First Nat'l Supermarkets, Inc.*, 112 F.R.D. 149, 154 (D. Mass. 1986); *Laxalt v. McClatchy*, 116 F.R.D. 438, 443 (D. Nev. 1987); see also *McIntyre v. Main St. & Main Inc.*, SACV 00-0745 2000 WL 33117274, at \*2 (N.D. Cal. Sept. 29, 2000). The rationale behind this

distinction is that if the identity of interviewed witnesses is disclosed, opposing counsel can infer which witnesses counsel considers important, revealing mental impressions and trial strategy. *See Laxalt*, 116 F.R.D. at 443. Such evaluations, impressions, and strategy are at the heart of the work product rule. The identity of witnesses is subject to qualified protection and thus opposing counsel may obtain disclosure based upon the requisite showing of need and undue hardship. *See Am. Floral Servs., Inc. v. Florists' Transworld Delivery*, 107 F.R.D. 258, 260 (N.D. Ill. 1985).

*In re MTI*, 2002 WL 32344347 at \*3.

Pfizer offers no argument concerning need or undue hardship. Pfizer will suffer no apparent hardship in not learning the identity of Plaintiffs' interviewee. None of the cases Pfizer cites involves the identity of pre-suit investigation interviewees. *Patterson v. Burge*, No. 03 C 4433, 2007 WL 1317128 (N.D. Ill. May 4, 2007), is a recent opinion by Magistrate Judge Brown involving a parolee who was working as an investigator for two journalism professors at Northwestern University. *Patterson*, 2007 WL 1317128 at \*1. Judge Brown ruled that the parolee/investigator was required to testify about facts he learned while investigating claims of wrongful convictions for the two journalism professors. *Id.* at 6. *Am. Floral Servs.* Involved a discovery dispute in which plaintiff AFS suspected that defendant Teleflora was withholding documents and information. *Am. Floral Servs.*, 107 F.R.D. at 259. Plaintiff confirmed its suspicions by contacting two Teleforma employees. *Id.* The court required plaintiff to disclose the names of these employees, but acknowledged that "the issue [of application of the work product doctrine] is not free from doubt." *Id.*, at 260. Finally, *Clark Equip. Co. v. Lift Parts Mfg. Co.*, No. 82 C 4585, 1985 WL 2917 (N.D. Ill. Oct 1, 1985), does not appear to involve the issue of a pre-suit interviewee by counsel.

**E. DOCUMENTS REGARDING SPECIFIC OFF-LABEL PRESCRIPTIONS ARE NOT DISCOVERABLE.**

Producing the private medical records of Plaintiffs' beneficiaries is unduly burdensome because it unnecessarily violates the privacy of third parties, who have not brought this litigation.

As set forth above, *see supra* Section B, the medical records of fund beneficiaries has no or little relevance to Plaintiffs' claims. Under Plaintiffs' prior Complaint, these records were outside of Plaintiffs care, custody and control. Now, these records remain outside of Plaintiffs' care, custody and control, and are not even relevant to the issue of damages. In *Neurontin*, where plaintiffs similarly agreed to prove damages solely by statistical methods, the court held that it would be unduly burdensome to produce patients' medical records:

After hearing, I conclude that the burden, expense and invasion of privacy of the proposed discovery outweighs its likely benefit. See Fed. R. Civ. P. 26 (b)(2) . . . If either party intends to call a treating physician to give an opinion on effectiveness, sanitized patient records shall be produced to the extent the physician is relying on his experience with treating that patient (as opposed to a clinical trial).

See Order, *In Re Neurontin Marketing, Sales Practices*, 1:04-cv-10981-PBS (September 27, 2007).

Similarly, the court in *Riley v. Walgreen Co.* 233 F.R.D. 496, 501 (S.D. Tex. 2005) held that a pharmacy did not have to turn over names and prescription information of its customers in litigation brought by plaintiff alleging that his prescription was improperly filled. Plaintiff requested the name and prescription data of other patients to determine if the pharmacy made other prescription-filling errors. *Id.* The court did not require the production of such information, holding: "Patient prescription drug orders and medication records contain highly sensitive and personal information . . . Given the extremely sensitive information at issue, the court agrees that both redaction of names and a confidentiality agreement are appropriate." *Id.* In this case, the privacy concerns of beneficiaries far outweigh the importance of their medical records to this litigation.

**CONCLUSION**

For all the aforementioned reasons, Plaintiffs respectfully request that Pfizer's Motion to Compel be denied.

Dated: September 19, 2007

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I, George S. Bellas, certify that on this 19<sup>th</sup> day of September, 2007, a true and correct copy of Plaintiffs' Opposition to Pfizer's Motion to Compel Plaintiffs to Provide Documents, Unredacted Claims Records, and Responses Concerning Pfizer's Proprietary Material was filed electronically and served by electronic mail, facsimile and first-class mail upon the following counsel of record:

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## **EXHIBIT U**

UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

SOUTHERN ILLINOIS LABORERS' AND )  
EMPLOYERS HEALTH AND WELFARE )  
FUND; NECA-IBEW WELFARE TRUST )  
FUND; MIDWESTERN TEAMSTERS )  
HEALTH AND WELFARE FUND; THE )  
WELFARE FUND OF TEAMSTERS )  
LOCAL UNION 863; PLUMBERS & )  
PIPEFITTERS LOCAL UNION 630 )  
WELFARE TRUST FUND; CLEVELAND )  
BAKERS AND TEAMSTERS HEALTH )  
AND WELFARE FUND; ELECTRICAL )  
WORKERS BENEFIT TRUST FUND; FIRE )  
& POLICE RETIREE HEALTH CARE )  
FUND, SAN ANTONIO, LABORERS' )  
DISTRICT COUNSEL BUILDING AND )  
CONSTRUCTION HEALTH AND )  
WELFARE FUND; LABORERS' DISTRICT )  
COUNCIL HEAVY AND HIGHWAY )  
UTILITY HEALTH AND WELFARE )  
FUND, and NEW YORK CITY POLICE )  
SERGEANTS BENEVOLENT )  
ASSOCIATION HEALTH & WELFARE )  
FUNDS, individually, and on behalf of all )  
others similarly situated, )  
Plaintiffs, )  
v. )  
PFIZER INC., )  
Defendant. )

NO. 06-CV-1818

JUDGE JOHN W. DARRAH

MAGISTRATE JUDGE  
GERALDINE SOAT BROWN

**DEFENDANT PFIZER INC'S OPPOSITION TO PLAINTIFFS' OBJECTIONS TO  
MAGISTRATE JUDGE BROWN'S ORDER DATED DECEMBER 21, 2007  
GRANTING PFIZER'S MOTION TO COMPEL**

Defendant Pfizer Inc (“Pfizer”) respectfully submits this memorandum in opposition to Plaintiffs’ Objections to Magistrate Judge Brown’s Order of December 21, 2007 (the “Order”).

### **PRELIMINARY STATEMENT**

Despite their claims for billions of dollars from Pfizer, and Pfizer’s production of hundreds of thousands of documents, Plaintiffs believe that they are immune from the rigors of discovery. Indeed, they have repeatedly attacked Judge Brown’s rulings whenever she has required them to comply with their long-overdue discovery obligations. There can be no doubt that Judge Brown’s Order granting Pfizer’s motion to compel Plaintiffs (or the “Funds”) to produce (i) long-overdue discovery, including numerous categories of documents that Plaintiffs had repeatedly promised to provide, (ii) unredacted prescription claims records, and (iii) information about how they obtained certain confidential and proprietary Pfizer documents, is fully supported by the record and the law. In fact, Plaintiffs expressly do not object to Judge Brown’s ruling rejecting their privilege objection and directing them to provide the requested information about the misappropriated documents. In addition, with regard to the majority of Pfizer’s outstanding discovery requests, Plaintiffs do not dispute Judge Brown’s relevance ruling.

Plaintiffs limit their objections to two, equally defective challenges, both of which rely on repeated mischaracterizations of Judge Brown’s Order and their own pleadings. First, Plaintiffs assert that Judge Brown erred by ordering them to produce or “create” documents that do not exist or over which they do not have control. The Order does no such thing. It directs Plaintiffs to comply with their own representations in their Complaint and discovery responses and produce responsive documents that should have been exchanged over one year ago. Moreover, Plaintiffs have submitted, for the first time, a hodge podge of carefully worded affidavits that were prepared only in an attempt to avoid Judge Brown’s Order, rather than in response to Pfizer’s discovery requests or motions to compel. These belated, self-serving, and conclusory affidavits were never part of the record before Judge Brown, and Pfizer certainly never had the opportunity to test the veracity of any statements therein. In any event, the affidavits do not establish any error in the Order, were not given to Judge Brown, and should be disregarded.

Second, Plaintiffs once again challenge Judge Brown’s finding, which is based on an extensive record and analysis of the pleadings, that participant- and prescription-specific information remains discoverable under the Second Amended Complaint (“SAC”) and is not unduly burdensome for the Funds to provide. This finding is well supported by the Funds’ own

pleadings and discovery responses and entirely consistent with the Federal Rules.

Notwithstanding Plaintiffs' incredible claim that their SAC includes a "streamlined" damages theory, in an effort to avoid producing virtually any discovery, or their misplaced complaints of burden (in a case where they are seeking thirty billion dollars and have demanded and received hundreds of thousands of documents from Pfizer), the participant- and prescription-specific discovery is squarely related, not just to damages, but to Plaintiffs' liability and causation allegations. As Judge Brown recognized, Pfizer is not bound by Plaintiffs' theory of damages. Moreover, as Judge Brown properly held, Plaintiffs' state privacy law objections have no merit in this federal question action, in which a HIPAA-compliant protective order is in place.

Because Plaintiffs cannot show that Judge Brown's Order "is clearly erroneous or is contrary to law," Fed. R. Civ. P. 72(a), this Court should overrule their objections in their entirety and affirm the Order.

### **RELEVANT FACTS**

On September 7, 2007, after months of trying to obtain discovery, Pfizer filed the motion to compel that is the subject of Judge Brown's Order. *See* Pfizer's Motion to Compel [D.E. 133]. The basis for Pfizer's motion with regard to outstanding documents was simple: over a year after having agreed to provide documents responsive to several dozen targeted requests, the majority of Pfizer's requests remained outstanding, and seven of the eleven Funds had produced fewer than 400 pages. *See id.* at 3-9. Indeed, several Funds had produced fewer than 100 pages, in contrast to the hundreds of thousands of pages produced by Pfizer. *See id.* at 4. Pfizer had previously documented the vast deficiencies in Plaintiffs' responses to Pfizer's requests for documents in an earlier motion to compel and related filings before Judge Brown. *See* Pfizer's Motion to Compel Plaintiffs to Provide Proper Responses to Interrogatories and Requests for Production of Documents [D.E. 77]; Pfizer's Notice of Outstanding Discovery Disputes [D.E. 90]; Pfizer's Supplement to Notice of Outstanding Discovery Disputes [D.E. 91]. Pfizer withdrew its prior motion in June 2007, based on Plaintiffs' assurances, to Pfizer and to Judge Brown, that proper discovery responses, already many months overdue, would be forthcoming. *See* 6/13/07 Minute Order [D.E. 92]. Plaintiffs never honored those commitments.

In their opposition to Pfizer's motion to compel [D.E. 140], the Funds ignored the vast majority of the discovery requests that were the subject of Pfizer's motion and focused on objecting to the few requests concerning participant information. They did not assert, by

affidavit or otherwise – as they purport to do now in affidavits that were never before Judge Brown – that each of the Funds had produced all documents in its custody or control that were responsive to the large number of outstanding requests seeking non-participant-specific information and documents.<sup>1</sup> To the contrary, the Funds stated in their opposition that their “document production thus far” was based on Judge Brown’s prior discovery orders (directing them to respond to an *interrogatory* by identifying off-label Lipitor prescriptions) (Pls.’ Opp. [D.E. 140] at 2), rather than on the actual document requests served by Pfizer a year earlier. As Judge Brown’s Order indicates, those requests seek a number of categories of relevant documents that are distinct from the prescription-specific information addressed by her prior orders, including:

Documents sufficient to determine the amount of damages alleged (Doc. Req. 10); documents regarding Plaintiffs’ initial determination to pay for Lipitor (Doc. Req. 19); documents provided to participants or physicians by Plaintiffs regarding reimbursement or payment for Lipitor (Doc. Req. 21); any statement about Lipitor that Plaintiffs relied upon (Doc. Req. 29); and any Lipitor ad or promotional piece relied upon by Plaintiffs (Doc. Req. 30).

Order at 8. In any event, the fact that they may have complied with a few obligations, or do not have a few categories of documents, is no reason to vitiate Judge Brown’s Order.

With regard to Pfizer’s requests for certain prescription- or participant-specific documents, including unredacted Lipitor prescription claims records, Plaintiffs opposed Pfizer’s motion to compel on the ground that such information was irrelevant to the newly-filed SAC and that it would be unduly burdensome for them to produce the relevant documents. Plaintiffs had amended their complaint in an admitted attempt to avoid discovery directed by Judge Brown. The SAC, however, is substantially similar to, and includes all of the primary allegations found in, their two prior complaints, including Plaintiffs’ claims that Pfizer promoted Lipitor for off-label purposes and that each of the Funds paid for improper or “unnecessary” off-label Lipitor prescriptions. *See, e.g.*, SAC ¶¶ 4, 5, 8-18, 70, 73, 80, 108-77, 220, 227, 241, 260, 270, 274, 283, 290, 295, 301, 305. Plaintiffs did not provide any sworn statements or other evidence in support

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<sup>1</sup> In fact, a number of the Funds’ affidavits confirm that they had not produced to Pfizer, at the time of its motion, all documents that they believe are responsive and in their control. *See, e.g.*, Aff. of Kathryn Zizza of the Welfare Fund of Teamsters (Objections Ex. D-6) ¶ 16(c); Aff. of James Bounds of Fire & Police Retiree Health Care Fund (Objections Ex. D-7) ¶ 8; Aff. of Robert G. Cadwell of Electrical Workers Benefit Trust Fund (Objections Ex. D-11) ¶¶ 7, 12.

of their arguments that it would be too burdensome for each of the Funds to obtain the medical and prescription records, such as those that the “test” Fund, Plumbers & Pipefitters, had already obtained, pursuant to an earlier order by Judge Brown. Similarly, Plaintiffs did not provide any record support for their claim, in their opposition to Pfizer’s motion, that “for many Funds ‘control’” – which they agreed includes the legal right to obtain – “either does not exist or is, at best, unclear.” Pls.’ Opp. at 4. In fact, as Pfizer demonstrated in its reply, the record includes substantial evidence of such control:

A number of the Funds have represented in their responses to requests for admission both that they maintain medical records for participants and that they receive medical records concerning participants in connection with their payment or reimbursement for pharmacy benefits.<sup>2</sup> In addition, plan documents and contracts produced by those Funds who have actually provided such documents confirm that they have the right to obtain and use their participants’ medical information for a number of purposes, including to adjudicate claims and in connection with a lawsuit or pursuant to a court order.<sup>3</sup>

Pfizer’s Reply [D.E. 141] at 11-12. Moreover, Plaintiffs’ counsel had previously conceded that participant information – including the names of participants who received Lipitor prescriptions – was covered by, and therefore discoverable under, the parties’ existing HIPAA-compliant protective order, which has been entered by this Court [D.E. 48]. *See* 6/13/07 Tr. [D.E. 95] at 34. The protective order was negotiated specifically to permit disclosure of participant information.

Judge Brown issued her Order granting Pfizer’s motion to compel after full briefing and oral argument on the motion. The Order directs the Funds to produce documents responsive to Pfizer’s outstanding requests – documents that, as Judge Brown recognized, the Funds had previously agreed to provide – as well as unredacted participant information. It does not, as

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<sup>2</sup> *See, e.g.*, First Amended and Supplemental Responses and Objections to Defendant Pfizer Inc.’s First Request for Admission to Plaintiff Teamsters Local Union 863 (attached as Ex. 3 to D.E. 141), Nos. 8-9. Plaintiffs Plumbers and Pipefitters, Electrical Workers Benefit Trust Fund, Laborers’ District Council Building and Construction Health and Welfare Fund, and Laborers’ District Council Heavy and Highway Utility Health and Welfare Fund provided the same responses to Requests Nos. 8 and 9. Cleveland Bakers has also indicated, in response to Request No. 8 that it maintains medical records for its participants.

<sup>3</sup> *See, e.g.*, Cleveland Bakers Notice of Privacy Practices (attached as Ex. 4 to D.E. 141); IBEW-NECA Notice of Privacy Policy, *available at* <http://www.neca-ibew.org/welfare/NoticePrivacyPolicy.pdf> (attached as Ex. 5 to D.E. 141); Midwestern Teamsters 2005 Summary Plan, Use and Disclosure of Your Protected Health Information (attached as Ex. 6 to D.E. 141); Southern Illinois Laborers 2005 Summary Plan, Privacy Amendment (attached as Ex. 7 to D.E. 141).

Plaintiffs assert, compel them to produce documents that “do not exist” or that “must be *created*.” Objections at 3; *id.* at 7. Plaintiffs’ after-the-fact claims about burden and impossibility simply do not comport with the fulsome record and history of events that were before Judge Brown.

### **ARGUMENT**

#### **I. RULE 72(A) REQUIRES PLAINTIFFS TO ESTABLISH THAT JUDGE BROWN’S ORDER IS CLEARLY ERRONEOUS OR CONTRARY TO LAW**

“The Federal Rules of Civil Procedure grant magistrate judges broad discretion in resolving discovery disputes.” *Ocean Atl. Woodland Corp. v. DRH Cambridge Homes, Inc.*, No. 02 C 2523, 2004 U.S. Dist. LEXIS 4698, at \*9 (N.D. Ill. Mar. 22, 2004). A district court may modify or reverse a magistrate judge’s discovery order only if it finds the ruling to be “clearly erroneous or . . . contrary to law.” Fed. R. Civ. P. 72(a); *see also* 28 U.S.C. § 636(b)(1)(A). The law in this Circuit is very clear: “The district court must review the magistrate judge’s ruling under the ‘clear error standard,’ which ‘means that the district court can overturn the magistrate judge’s ruling only if the district court is left with the definite and firm conviction that a mistake has been made.’” *FTC v. Pac. First Benefit, LLC*, 361 F. Supp. 2d 751, 754 (N.D. Ill. 2005) (quoting *Weeks v. Samsung Heavy Indus. Co.*, 126 F.3d 926, 943 (7th Cir. 1997)); *see also Rubin v. Islamic Republic of Iran*, No. 03 CV 9370, 2007 U.S. Dist. LEXIS 54983, at \*7 (N.D. Ill. July 26, 2007) (“Review is deferential, and a magistrate judge’s ruling will be set aside or modified only if the ruling is clearly mistaken.”); *accord Hutchinson v. Blagojevich*, No. 04 C 2947, 2006 U.S. Dist. LEXIS 36071, at \*6-7 (N.D. Ill. Apr. 12, 2006). As these authorities confirm, Rule 72(a) “sets the hurdle high.” *Finwall v. City of Chicago*, 239 F.R.D. 504, 506 (N.D. Ill. 2006); *see also Am. Hardware Mfrs. Ass’n. Reed Elsevier Inc.*, No. 03 C 9421, 2007 U.S. Dist. LEXIS 35352, at \*5, \*5-10 (N.D. Ill. May 11, 2007) (noting that objectors “face a high burden in their attempt to show that [a magistrate judge’s] ruling was in error”).

As established below, Plaintiffs have not identified any error in Judge Brown’s rulings that would justify disturbing her Order under Rule 72(a)’s deferential standard. Plaintiffs’ arguments implying that Judge Brown acted without record support, beyond her jurisdiction, and without regard to the case law or Federal Rules are fanciful. In fact, courts in this District have repeatedly upheld Judge Brown’s discovery rulings. *See, e.g., Jackson v. City of Chicago*, No. 03 C 8289, 2006 U.S. Dist. LEXIS 56675, at \*13, \*28-37 (N.D. Ill. July 31, 2006); *Pac. First*

*Benefit, LLC*, 361 F. Supp. 2d at 755-57; *Smith v. Sprint Commc'ns Co.*, No. 99 C 3844, 2003 U.S. Dist. LEXIS 2803, at \*6, \*9 (N.D. Ill. Feb. 26, 2003).

**II. JUDGE BROWN'S ORDER DIRECTING PLAINTIFFS TO PRODUCE PREVIOUSLY-AGREED DOCUMENTS AND UNREDACTED INFORMATION IS NEITHER CLEARLY ERRONEOUS NOR CONTRARY TO LAW**

Judge Brown correctly determined both that Pfizer's outstanding document requests remain relevant, and that it would not be unduly burdensome for Plaintiffs to comply with their commitment to produce responses. She also properly rejected certain Plaintiffs' objections to providing unredacted participant information, given the parties' HIPAA-compliant protective order and the fact that several Plaintiffs had already provided unredacted information. In their attempt to create an impression of error in her straightforward and well-reasoned rulings, Plaintiffs rely on: (i) unsupportable statements about the nature of their own allegations; (ii) a twisted and nonsensical interpretation of the Order; (iii) a legal argument that they never asserted before Judge Brown or Pfizer; (iv) untimely affidavits from the Funds that were similarly not part of the record before Judge Brown and were created only in response to the Order; and (v) an erroneous construction of the laws governing the right to obtain protected medical information. These tactics do not establish that Judge Brown's Order was erroneous or contrary to law.

**A. The Order Properly Directs Plaintiffs to Produce Documents Within Their Control; It Does Not Order Plaintiffs to "Create" Documents That Do Not Exist**

This Court should also reject Plaintiffs' mischaracterization of Judge Brown's Order as directing them to "create" and produce documents that do not exist. *See* Objections at 3 ("Many of the documents the Order compels just do not exist. They must be *created* by Plaintiffs . . .") (emphasis in original); *id.* at 7 ("Plaintiffs must create reports in order to comply with the Order.") (emphasis in original). Judge Brown made no such ruling and nothing in her Order suggests otherwise. Judge Brown merely directed the Funds to produce, pursuant to their own commitments in their discovery responses, and as required by the Federal Rules, responsive documents in their custody or control.<sup>4</sup> That some of the responsive documents, as discussed

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<sup>4</sup> As noted, Plaintiffs had agreed, in exchange for Pfizer's agreement to withdraw its earlier motion to compel, to produce the vast majority of requested documents that were in their possession, custody, or control.

below, are not currently in the Funds' possession, but are, instead, within the Funds' legal capacity to obtain, does not mean those documents do not exist or must be "created."

Plaintiffs' contention that that "[t]he Order erroneously compels the production of documents that Magistrate Judge Brown 'expects' would be in Plaintiffs' possession without requiring Pfizer to carry its burden of establishing control" (Objections at 7 (citing Order at 9)), is similarly inaccurate. As a preliminary matter, Plaintiffs never argued before Judge Brown that Pfizer had, and did not meet, the burden of establishing Plaintiffs' control over the requested documents. That argument, like Plaintiffs' other new arguments, was waived. *See Murr v. United States*, 200 F.3d 895, 902 n.1 (6th Cir. 2000) ("[A]bsent compelling reasons, [the Magistrate Judge Act] does not allow parties to raise at the district court stage new arguments or issues that were not presented to the magistrate."); *Marshall v. Chater*, 75 F.3d 1421, 1426 (10th Cir. 1996) ("Issues raised for the first time in objections to the magistrate judge's recommendation are deemed waived."); *accord Hamilton v. Am. Corrective Counseling Servs., Inc.*, No. 3:05-CV-434, 2007 U.S. Dist. LEXIS 28322, at \*3-4 (N.D. Ind. Apr. 13, 2007) ("An objecting party generally may not raise new issues that weren't presented to the magistrate judge."); *Columbia Gas Transmission Corp. v. Rockwell Enters., Inc.*, No. 1:06 CV 2989, 2007 U.S. Dist. LEXIS 85093, at \*7-8 (N.D. Ohio Nov. 9, 2007) (overruling objections based on arguments and affidavit not submitted to the magistrate judge); *cf. Anna Ready Mix, Inc. v. N.E. Pierson Constr. Co.*, 747 F. Supp. 1299, 1303 (S.D. Ill. 1990) ("[T]he proper functioning of the magistrate system requires that, absent compelling reasons, the magistrate hear all arguments the parties wish to make."). Accordingly, the Funds' objections on the grounds that "[the] Order cites no case to the contrary" and does not include analysis on their new burden argument (Objections at 7) must be rejected because Plaintiffs never articulated that argument or cited before Judge Brown any of the authorities they do now.<sup>5</sup>

More importantly, however, with the exception of certain participant- and prescription-specific records discussed below, the Funds never asserted before Judge Brown that they did not have control over any of the many categories of documents at issue. *See* Order at 7 ("Plaintiffs'

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<sup>5</sup> Plaintiffs also improperly argue for the first time that "Pfizer could have served an interrogatory asking Plaintiffs to identify or provide an inventory detailing the documents they control." Objections at 8. Of course, that would have been a ridiculous way to proceed after Pfizer asked for certain documents and Plaintiffs agreed to produce them.

Opposition [to Pfizer's motion to compel] [did] not attempt to discuss any individual request."). To the contrary, in their responses to the relevant requests for production, which *were* before Judge Brown, the Funds had already *agreed* to produce responsive documents "within their possession, custody, or control." *See* Pfizer's Motion to Compel [D.E. 133] at 5-9; Order at 7-8. Pfizer's motion to compel did not, therefore, "rest[] on bald assertions that Plaintiffs have, or have control over, the documents it seeks." Objections at 4. It relied on the Funds' own discovery responses and on the Funds' counsel's repeated assurances, including those made to obtain Pfizer's agreement to withdraw its earlier motion to compel, that, consistent with those responses, additional documents would be forthcoming. Moreover, the "test" Fund produced participant-specific information and other Funds provided limited prescription data that was clearly in their control.

Those discovery responses and representations by counsel, together with the absence of any averment by any of the Funds that they *did not* actually possess or control any of the outstanding documents they had agreed to produce, plainly both: (i) satisfied any burden on Pfizer to make a threshold showing of control; and (ii) support Judge Brown's Order directing Plaintiffs to comply with their commitments and produce what they have. That the Funds have *now*, and only in response to Judge Brown's Order, submitted affidavits purporting to identify the responsive documents each Fund does and does not maintain or have a right to obtain, and to attest – despite counsel's previous, repeated representations that additional documents would be produced – that the Funds' current productions (many of which number only a few hundred pages or less) include all responsive documents within their custody or control, certainly does not make Judge Brown's ruling erroneous. Rather, the Funds' twelfth-hour affidavits support Pfizer's motion and Judge Brown's Order by confirming that the Funds had not previously attempted to fulfill their discovery obligations by producing the outstanding documents or affirmatively stating that they did not have them. *See, e.g., Innovative Piledriving Prods., LLC v. Oy*, No. 1:04-CV-453, 2005 U.S. Dist. LEXIS 14744, at \*2 (N.D. Ind. July 21, 2005). Rather than wasting more time with ill-advised objections, the Funds should simply produce the materials that they were ordered to produce.

**B. The Order Correctly Finds That Responsive Documents Involving Prescription and Participant Medical Information Remain Relevant, Are Within the Funds' Control, and Would Not Be Unduly Burdensome for the Funds to Produce**

In objecting to Judge Brown's Order to the extent it directs them to respond to outstanding document requests involving prescription and participant medical information, Plaintiffs repeat and incorporate their objections to Judge Brown's November 14, 2007, Order. *See* Objections at 11. Accordingly, Pfizer also refers to and incorporates its Opposition to Plaintiffs' Objections to the November 14, 2007, Order [D.E. 181]. Indeed, the Funds' current objections should fail for all of the same reasons as their objections to the earlier Order.

**1. The Documents Remain Relevant Under the SAC**

First, Judge Brown's December 21 Order does not, as Plaintiffs assert, "completely ignore[]" their argument that their amendment of the Complaint to allege a "price inflation" theory rendered discovery "relating to individual prescriptions of Lipitor . . . of marginal, if any, relevance." Objections at 2. To the contrary, Judge Brown's Order expressly considers and rejects that argument:

Plaintiffs' argument that discovery about their own experience in reimbursing their participants for Lipitor, and particularly Plaintiffs' payments for allegedly improper prescriptions for off-label purposes, is now irrelevant ignores some of Plaintiffs' own allegations in the Second Amended Complaint. (*See* Nov. 14 Order at 5-6.) The Second Amended Complaint asserts that Plaintiffs were the victims of a fraudulent marketing scheme by Pfizer for the over-promotion of Lipitor, which, Plaintiffs allege, "increased the demand and expanded the market for Lipitor, artificially driving up Lipitor's price and thereby damaging the Plaintiffs. . . ." (Jt. Mot. at 3.) Additionally, as further described in the November 14 Order, the Second Amended Complaint continues the allegations that Plaintiffs paid for an increased number of Lipitor prescriptions as a result of the scheme. (Nov. 14 Order at 6.) Thus, documents that would demonstrate, for example, the amounts that Plaintiffs paid for Lipitor over time, and whether Plaintiffs actually paid for an increased number of prescriptions of Lipitor as a result of Pfizer's alleged marketing scheme, are well within the scope of discovery under the Federal Rules of Civil Procedure.

Order at 8. The sections of the November 14 Order that Judge Brown references above include numerous citations to paragraphs in Plaintiffs' SAC that demonstrate that they continue to allege that they have paid for unnecessary off-label prescriptions for Lipitor. *See, e.g.*, SAC ¶¶ 8-18. Those allegations directly refute Plaintiffs' repeated mischaracterization of their complaint, including their assertion in their current objections that "[t]he SAC alleges only that Pfizer's false and misleading promotion of Lipitor resulted in Lipitor's price being higher than it would

have been without such promotion.” Objections at 5. As Judge Brown found, because the underlying premise of the SAC remains Plaintiffs’ claim that Pfizer’s marketing caused the Funds and others to pay for unnecessary off-label Lipitor prescriptions, Pfizer is entitled to request and obtain documents relating to the alleged off-label prescriptions for which the Funds claim to have paid. *See* Order at 11 (“[T]he information Pfizer seeks goes directly to the question of whether Plaintiffs paid for more Lipitor prescriptions than necessary and whether Plaintiffs paid too much for Lipitor. That is the heart of Plaintiffs’ claims.”); *id.* at 12 (“Pfizer has a right to discovery that will test the validity of Plaintiffs’ allegations that they paid for an ‘artificially increased number of Lipitor prescriptions.’”) (quoting SAC ¶ 4).

Plaintiffs’ belief that such documents and information are of limited relevance because *they* do not intend to rely on them in attempting to prove their case does not, as Judge Brown held, limit Pfizer’s right to obtain them. *See id.* at 12. Nor does the “willingness” of a few courts “to rely on statistical modeling in third-party payor cases” (Objections at 13)<sup>6</sup> support the Funds’ position that Pfizer should be precluded from obtaining discovery on anything other than Plaintiffs’ theory of damages and unidentified statistical model.<sup>7</sup>

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<sup>6</sup> Plaintiffs disingenuously assert that “Judge Brown rejected Plaintiffs’ proposed approach to establishing damages.” Objections at 4. Judge Brown has held only that Pfizer’s right to obtain relevant discovery is not confined to Plaintiffs’ proposed approach; she has never precluded Plaintiffs from pursuing that approach, nor ruled on its merits.

<sup>7</sup> As Pfizer has previously noted (*see* Opp. to Objections to Nov. 14 Order [D.E. 181] at 11), Judge Saris in *In re Neurontin*, on which the Funds rely, *denied* plaintiffs’ motion to certify classes of consumers and third-party payors seeking to recover for purchases of Neurontin for off-label purposes. *In re Neurontin Mktg. & Sale Practices Litig.*, 244 F.R.D. 89, 115 (D. Mass. 2007). Although the denial was without prejudice, the court identified a number of problems with plaintiffs’ proposed aggregate statistical approach, including the inability to identify “which doctors prescribed Neurontin based on [defendant’s] promotion as opposed to lawful off-label prescribing by a doctor who is exercising his own medical judgment.” *Id.* at 113; *see also id.* at 114-15 (finding statistical approach “problematic” with respect to third-party payor claims since it was not clear that they could “distinguish between payments for on- and off-label prescriptions”). Thus, while *Neurontin* may offer evidence of the use, albeit failed, of a statistical methodology, it does not provide support for limiting Pfizer’s right to obtain the kind of discovery that Judge Saris’s opinion indicates is not only relevant but critical to the prosecution and defense of claims like the Funds’. Similarly, in *In re Zyprexa*, 493 F. Supp. 2d 571, 579 (E.D.N.Y. 2007), Judge Weinstein ruled only that plaintiffs may *try* to employ a theory of aggregate proof. He emphasized that it was “not clear that plaintiffs can prove any damages, whether they attempt to prove overpayment on a case-by-case basis . . . or through statistical analysis,” *id.* at 576 (emphasis added), and did not foreclose discovery of individual prescription information, as Plaintiffs seek to do here.

## 2. Plaintiffs Have Not Established Undue Burden

Plaintiffs have similarly failed to identify any error in Judge Brown's finding that it would not be unduly burdensome, under the factors set out in Rule 26(b)(2)(C)(iii), for the Funds to produce responsive documents containing (unredacted) prescription and medical information. *See* Order at 11. Judge Brown properly held that Plaintiffs failed to adequately support their undue burden argument with anything other than the unsworn and conclusory statements of their counsel. *See id.* at 10; *see also In re Sulfuric Acid Antitrust Litig.*, 231 F.R.D. 351, 360-61 (N.D. Ill. 2005) ("In order to demonstrate undue burden, the plaintiffs must provide affirmative proof in the form of affidavits or record evidence. . . . [T]he *ipse dixit* of counsel . . . is not sufficient.") (citations omitted). Plaintiffs do not and cannot dispute that they did not provide a single affidavit from any Fund, or any other evidence, to support the undue burden arguments in their opposition to Pfizer's motion to compel. They attempt to evade the impact of this omission by arguing that Pfizer had not established Plaintiffs' control over the documents and information at issue. *See* Objections at 9-10. As noted above, because Plaintiffs did not raise this argument before Judge Brown, it should be deemed waived here. *See supra* Part II.A.

But even if Plaintiffs had raised the argument and Pfizer did have such a burden, it met it in a number of ways. In particular, Pfizer provided both the Funds' own discovery responses, in which they agreed to produce documents containing the requested prescription and medical information, and numerous examples of the Funds' own statements and plan documents indicating that they maintain or have the right to obtain such information. Pfizer's reply brief in further support of its motion to compel, for example, provided record citations establishing that many of the Funds have admitted that they maintain and receive medical records, and that plan documents and contracts for the Funds who actually produced them indicate that those Funds have the legal right to obtain and use their participants' medical information for a number of purposes, including to adjudicate claims, or in connection with a lawsuit or court order.<sup>8</sup> *See*

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<sup>8</sup> Indeed, the letter Plaintiffs sent to doctors in connection with its collection of medical records for Plumbers & Pipefitters advised doctors that: "our members have authorized us, in our plan documents, to obtain such . . . information when the Fund is making a claim based on benefits the Fund paid on behalf of its members;" "HIPAA permits disclosure of protected health information in a judicial proceeding"; and "all protected health information exchanged between the parties in the case is subject to a HIPAA-authorized Confidentiality Agreement." [Ex. A to D.E. 106]

Pfizer's Reply [D.E. 141] at 12; *supra* Relevant Facts at 4.<sup>9</sup> Plaintiffs never disputed these assertions or citations.<sup>10</sup> Accordingly, Judge Brown did not err in finding that Plaintiffs had the burden of demonstrating, with evidentiary support, that it would be unduly burdensome for them to produce documents that the record indicated were in their control. Nor did she err in finding that Plaintiffs had not provided any such evidence and, therefore, had not met that burden.<sup>11</sup>

### 3. Plaintiffs' Privacy Objections Are Erroneous

Judge Brown also correctly rejected both the privacy strand of Plaintiffs' burden claims and their privacy objections to providing unredacted participant information. It is well established that HIPAA permits parties to obtain, and non-party entities to disclose, medical records and other protected health information during discovery where, as here, the information is relevant and the court has entered a HIPAA-compliant protective order. *See Nw. Mem'l Hosp.*

<sup>9</sup> As Pfizer has previously demonstrated, "it is well-settled that a party need not have actual possession of [discoverable information] to be deemed in control of [it]; rather, the test is whether the party has a legal right to obtain [it]." *Dexia Credit Local v. Rogan*, 231 F.R.D. 538, 542 (N.D. Ill. 2004) (internal quotation marks and citation omitted); *accord Engel v. Town of Roseland*, No. 3:06 CV 430, 2007 U.S. Dist. LEXIS 73645, at \*10-11 (N.D. Ind. Oct. 1, 2007). *See also* Opp. to Objections to Nov. 14 Order [D.E. 181] at 12.

<sup>10</sup> In direct contrast to this case, where Pfizer offered substantial evidence of the Funds' control over the documents and information at issue, and Plaintiffs failed to dispute that evidence with affidavits or other evidence, the moving parties in the cases on which Plaintiffs relied failed to provide *any* evidence of the opposing parties' control over the documents at issue and the opposing parties provided *sworn statements* that they did not have control. *See Technical Concepts, L.P. v. Cont'l Mfg. Co.*, No. 92 C 7476, 1994 U.S. Dist. LEXIS 7815, at \*4-5 (N.D. Ill. June 10, 1994) (moving party "offer[ed] no evidence in the record demonstrating [the] claimed agency relationship or ability to retrieve documents" while opposing party provided affidavit from president of the company denying any right to obtain them); *Sparks Tune-Up Ctrs., Inc. v. Panchevre*, No. 90 C 4369, 1991 U.S. Dist. LEXIS 7441, at \*6-7 (N.D. Ill. June 3, 1991) (defendant "swore under oath that he did not possess or control the documents" while plaintiff "offer[ed] no facts to support [the] theory" that defendant had control over them).

<sup>11</sup> Moreover, contrary to their contention, the affidavits Plaintiffs have just submitted do not establish that "Plaintiffs do not possess or control the patient specific medical records compelled by the Order." Objections at 11 n.10. Rather, the majority of them confirm that Plaintiffs do have contractual rights to obtain such records. *See, e.g.,* Aff. of John Long, Esq. of Southern Illinois Laborers (Objections Ex. D-1) ¶ 14(c) & Attachments; Aff. of John Long, Esq. of NECA-IBEW (Objections Ex. D-2) ¶ 14(c) & Attachments; Aff. of Britt W. Sowle, Esq. of Midwestern Teamsters (Objections Ex. D-3) ¶ 14(c) & Attachments; Aff. of Kathryn Zizza of the Welfare Fund of Teamsters (Objections Ex. D-6) ¶ 16(c); Aff. of James Bounds of Fire & Police Retiree Health Care Fund (Objections Ex. D-7) ¶ 17(c); Aff. of Alan Parham of Laborers' District Council Heavy and Highway Utility (Objections Ex. D-8) ¶ 17(c) & Attachments; Aff. of Alan Parham of Laborers' District Council Building and Construction (Objections Ex. D-9) ¶ 17(c) & Attachments; Affidavit of Robert G. Cadwell of Electrical Workers Benefit Trust Fund (Objections Ex. D-11) ¶ 18(c) & Attachments.

*v. Ashcroft*, 362 F.3d 923, 924-25 (7th Cir. 2004) (citing and discussing the relevant HIPAA provisions, explaining that a “qualified protective order” permits the disclosure of protected information); *United States ex rel. Camillo v. Ancilla Sys., Inc.*, 233 F.R.D. 520, 522 (S.D. Ill. 2005) (“HIPAA permits protected health information to be revealed in response to a discovery request, if the parties . . . have asked the Court for a protective order.”); *accord Ligas v. Maram*, No. 05 C 4331, 2007 U.S. Dist. LEXIS 58911, at \*19 (N.D. Ill. Aug. 10, 2007); *Biedrzycki v. Town of Cicero*, No. 04 C 3277, 2005 U.S. Dist. LEXIS 16423, at \*15 n.3 (N.D. Ill. Aug. 8, 2005).<sup>12</sup> Indeed, Plaintiffs themselves asserted their right to obtain records under HIPAA in the letter they sent to obtain medical information for participants of Plumbers & Pipefitters. *See supra* note 8. Although Plaintiffs may have encountered a few delays and complications as a result of their own failure to follow the basic protocol of medical records collection in a post-HIPAA world by providing patient authorizations, and by waiting until the last minute to begin collecting documents, they were able to obtain numerous records even without authorizations, within a few weeks. The parties subsequently worked out and presented to Judge Brown an agreed letter to physicians that would accompany valid authorizations from Fund participants, thus greatly facilitating the records retrieval process.

In addition, as Judge Brown recognized, “[t]he Protective Order previously entered by the District Judge with the agreement of the parties specifically identified the ‘Names of customers or patients’ as information that could be designated ‘Confidential’ and held subject to the Protective Order.” Order at 12 (citation omitted). Plaintiffs have not, as Judge Brown noted, “argue[d] that the Protective Order is not sufficient or should be modified.” *Id.*

Finally, there is no merit to Plaintiffs’ objection to Judge Brown’s application of the Seventh Circuit’s decision in *Northwestern Memorial Hospital v. Ashcroft*, 362 F.3d 923. As Judge Brown observed, the Seventh Circuit expressly overruled the portion of the district court’s decision, on which Plaintiffs had relied in their opposition to Pfizer’s motion, that held that state laws may prohibit the disclosure of medical records that would otherwise be permitted by

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<sup>12</sup> Plaintiffs’ citation to *Remeron* for the argument that “producing medical records in violation of HIPAA ‘may subject the provider to civil and/or criminal penalties [under HIPAA],’” is misplaced. Objections at 14 (quoting *In re Remeron End-Payor Antitrust Litig.*, Nos. Civ. 02-2007, Civ. 04-5126, 2005 WL 2230314, at \*15 n.4 (D.N.J. Sept. 13, 2005)). The fact that a HIPAA-compliant protective order has been entered in this case means that providers would be *in compliance with*, not in violation of, HIPAA and federal law by disclosing the relevant records and information.

HIPAA. Order at 10. The Seventh Circuit expressly held that in federal question suits, like the instant RICO action, state laws governing medical records privileges that conflict with HIPAA are unenforceable. *See Ashcroft*, 362 F.3d at 925; *see also Ligas*, 2007 U.S. Dist. LEXIS 58911, at \*20 (“[I]n a federal question suit . . . , state privacy and privilege laws do not apply, regardless of whether the state law might be more restrictive than the applicable federal rule.”); *accord Camillo*, 233 F.R.D. at 522-23 (“[T]he Seventh Circuit ruled in *Northwestern Memorial Hospital v. Ashcroft* that a more restrictive state law cannot be used in a federal-question action . . . to hamstring the enforcement of federal law.”); *State Farm Mut. Auto. Ins. Co. v. Accurate Med., P.C.*, CV 2007-0051, 2007 U.S. Dist. LEXIS 34410, at \*2-3 (E.D.N.Y. May 10, 2007). As Judge Brown found, *Ashcroft* plainly supports Pfizer’s position that Plaintiffs cannot avoid their discovery obligations by raising the possibility that nonparties may improperly object to disclosure of records under state privacy laws.<sup>13</sup> The fact that Plaintiffs have asserted diversity jurisdiction, in addition to federal question jurisdiction, does not affect this conclusion. The discovery at issue is plainly relevant to Plaintiffs’ federal RICO claims, and the Seventh Circuit and other courts have demonstrated a clear “preference for federal privilege law when it conflicts with state privilege law,” including in cases asserting both federal and state law claims. *Biedrzycki*, 2005 U.S. Dist. LEXIS 16423, at \*19-20 (quoting 3 Jack B. Weinstein & Margaret A. Berger, *Weinstein’s Federal Evidence* § 501.02[2][c] at 501-14 (2d ed. 2005 & Supp. Feb. 2005)); *see also id.* at \*21-23 (ordering disclosure of medical records under federal law where records were relevant to federal claims; finding competing state law privileges inapplicable). Moreover, Plaintiffs never raised any state law issues during the parties’ negotiation of the protective order and have never challenged Pfizer’s discovery requests under any specific state law provisions. Finally, as noted, Plaintiffs and Pfizer worked out an agreed form letter to physicians that would enclose an authorization executed by the Fund participant for whom medical information is sought, thus avoiding potential objections by medical providers (which would, in any case, be legally unsupportable).<sup>14</sup>

<sup>13</sup> Plaintiffs’ attempt to distinguish and avoid the ruling in *Ashcroft* is notable, given their own recognition of it as controlling authority and direct (though misplaced) reliance on it in their objections to Judge Brown’s Order of November 14, 2007. *See Am. Objections to Nov. 14 Order* [D.E. 173] at 7 n.2.

<sup>14</sup> Plaintiffs’ reliance on *Riley v. Walgreen Co.*, 233 F.R.D. 496 (S.D. Tex. 2005) (Objections at 14) is misplaced. The court in that state law diversity action applied Texas’s law governing the disclosure of  
(cont’d)

**CONCLUSION**

For the foregoing reasons, Pfizer respectfully requests that the Court overrule Plaintiffs' Objections in their entirety and affirm Judge Brown's Order of December 21, 2007.

DATED: January 24, 2008

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patient information, rather than HIPAA, which controls here, in granting Walgreen's requests to provide the requested prescription records with patient names redacted and pursuant to a protective order, like that *already in effect here*. *Riley*, 233 F.R.D. at 501.

**CERTIFICATE OF SERVICE**

I, Andrew J. Jarzyna, an attorney, certify that on this 24th day of January, 2008, one true and correct copy of the foregoing OPPOSITION TO PLAINTIFFS' OBJECTIONS TO MAGISTRATE JUDGE BROWN'S ORDER DATED DECEMBER 21, 2007 GRANTING PFIZER'S MOTION TO COMPEL was served through this Court's electronic filing system upon the following counsel for Plaintiffs: George S. Bellas, gsb@cliffordlaw.com; Robert A. Clifford, rac@cliffordlaw.com; Sidney S. Liebesman, sliebesman@gelaw.com; Patrick J. O'Hara, patrick@cavanagh-ohara.com; and Thomas K Prindable, tkp@cliffordlaw.com.

/s/Andrew J. Jarzyna  
Andrew J. Jarzyna

## **EXHIBIT V**

UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

SOUTHERN ILLINOIS LABORERS' AND )  
EMPLOYERS HEALTH AND WELFARE )  
FUND; NECA-IBEW WELFARE TRUST )  
FUND; MIDWESTERN TEAMSTERS )  
HEALTH AND WELFARE FUND; THE )  
WELFARE FUND OF TEAMSTERS )  
LOCAL UNION 863; PLUMBERS & )  
PIPEFITTERS LOCAL UNION 630 )  
WELFARE TRUST FUND; CLEVELAND )  
BAKERS AND TEAMSTERS HEALTH )  
AND WELFARE FUND; ELECTRICAL )  
WORKERS BENEFIT TRUST FUND; FIRE )  
& POLICE RETIREE HEALTH CARE )  
FUND, SAN ANTONIO, LABORERS' )  
DISTRICT COUNSEL BUILDING AND )  
CONSTRUCTION HEALTH AND )  
WELFARE FUND; LABORERS' DISTRICT )  
COUNCIL HEAVY AND HIGHWAY )  
UTILITY HEALTH AND WELFARE )  
FUND, and NEW YORK CITY POLICE )  
SERGEANTS BENEVOLENT )  
ASSOCIATION HEALTH & WELFARE )  
FUNDS, individually, and on behalf of all )  
others similarly situated, )

Plaintiffs, )

v. )

PFIZER INC., )

Defendant. )

NO. 06-CV-1818

JUDGE JOHN W. DARRAH

MAGISTRATE JUDGE  
GERALDINE SOAT BROWN

**PFIZER INC'S REPLY IN FURTHER SUPPORT OF ITS MOTION TO COMPEL  
PLAINTIFFS TO PROVIDE DOCUMENTS, UNREDACTED CLAIMS RECORDS,  
AND RESPONSES CONCERNING PFIZER'S PROPRIETARY MATERIALS**

### PRELIMINARY STATEMENT

In their opposition, Plaintiffs simply ignore the vast majority of discovery requests and deficiencies that are the subject of Pfizer's motion to compel, filed after months of unsuccessful attempts by Pfizer to obtain this core discovery from Plaintiffs without judicial intervention.<sup>1</sup> Instead, Plaintiffs cherry-pick a few of the discovery requests concerning participant information, and then grossly mischaracterize the requests and their own Second Amended Complaint ("SAC") in an effort to create the demonstrably false impression that Pfizer's carefully tailored, and long-outstanding, discovery is no longer relevant. But, as this Court is well aware from the "black-lined" version of the SAC provided by Plaintiffs, the SAC is substantially similar to the First Amended Complaint ("FAC") and includes all of the primary allegations found in the FAC. Indeed 162 paragraphs in the SAC are *identical* to those in the FAC, and seventeen other paragraphs are the same, but for stylistic edits. There is no dispute that Plaintiffs have also expanded the scope of the case, and discovery, by *adding* 47 new paragraphs, primarily asserting that Pfizer failed to disclose health risks about Lipitor and made inaccurate claims that Lipitor was superior to other statins, and by adding three new counts – unjust enrichment, fraudulent misrepresentation, and negligent misrepresentation – based on those allegations. Of course, that is precisely why Plaintiffs' counsel told Judge Darrah, in connection with Plaintiffs' motion to

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<sup>1</sup> In the "facts" section of their opposition, Plaintiffs candidly note that "Plaintiffs' *document production thus far* has been in response to this Court's prior discovery orders that Plaintiffs produce documents in support of their former theory of damages." Pls.' Opp. at 2 (emphasis added). While this is a point about which Pfizer and Plaintiffs can agree, and it certainly explains why many of the Funds have produced less than 100 pages of documents after seventeen months of litigation, the fact is that Plaintiffs should have been producing the documents that are the subject of this motion starting over a year ago in response to Pfizer's discovery requests, and not only in response to this Court's recent Order compelling them to respond to an interrogatory. In contrast, Pfizer has diligently searched for, collected, and produced hundreds of thousands of pages of documents responsive to Plaintiffs' voluminous requests, and numerous non-parties, including research scientists, physicians, and medical education providers all across the country, have produced tens of thousands of documents in response to Plaintiffs' subpoenas.

amend, that the SAC “dovetails and overlaps” with the FAC and that Pfizer will face no prejudice because the discovery efforts conducted under the FAC will still be applicable.

Notwithstanding Plaintiffs’ efforts to impose their purportedly “streamlined” damages theory upon Pfizer to avoid producing virtually any discovery, or their misplaced complaints of burden (in a case where they are seeking \$30 billion dollars and have demanded hundreds of thousands of documents from Pfizer), the discovery that is the subject of Pfizer’s present motion, and that Plaintiffs agreed to produce months ago in exchange for Pfizer’s agreement to withdraw its prior motions to compel, is directly relevant and squarely related, not just to damages, but to the liability and causation issues alleged in both the FAC and SAC.<sup>2</sup>

Pfizer, like almost every court around the country, rejects Plaintiffs’ theory of damages. But even if Plaintiffs’ damages theory had validity, it would not foreclose discovery, and the discovery Pfizer seeks would be relevant to Pfizer’s challenge to that theory. Beyond that, Plaintiffs’ lawsuit charging Pfizer with conducting a fraudulent marketing scheme that caused them billions of dollars in damages is about more than just damages: to state a claim and recover against Pfizer, Plaintiffs will have to first prove liability and causation. Accordingly, Pfizer has requested, and should be permitted to obtain, discovery from Plaintiffs – such as that at issue on this motion – that is relevant to Plaintiffs’ claims and each element of their causes of action.

### **ARGUMENT**

#### **I. PLAINTIFFS’ OBJECTIONS ARE MERITLESS**

Plaintiffs claim that Pfizer’s discovery requests are “marginally relevant” or have “limited relevance” and that they impose an undue burden on Plaintiffs. As this Court is well

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<sup>2</sup> With the exception of their agreement to produce information regarding “the total amount each Plaintiff spent[t] on Lipitor” (Pls.’ Opp. at 10), Plaintiffs have not agreed that any of Pfizer’s discovery is relevant or agreed to produce even one page in response to Pfizer’s motion.

aware, the standard for determining relevance under Rule 26 is broad, and “only requires that [the requested] material lead to the discovery of admissible evidence . . . .” *Irwin Indus. Tool Co. v. Orosz*, No. 03 C 1738, 2004 U.S. Dist. LEXIS 4265, at \*7 (N.D. Ill. Mar. 17, 2004) (Darrah, J.). Additionally, it is *Plaintiffs’* burden, as the objecting party, to convince this Court that their objections and failures to respond are proper. *See Meyer v. S. Pac. Lines*, 199 F.R.D. 610, 612 (N.D. Ill. 2001) (“The burden rests upon the objecting party to show why a particular discovery request is improper.”); *accord xxTrading Techs. Int’l, Inc. v. eSpeed Inc.*, No. 04 C 5312, 2005 U.S. Dist. LEXIS 10686, at \*2 (N.D. Ill. Apr. 28, 2005).

As a preliminary matter, Plaintiffs waived any objections to relevance or burden when they agreed, in open Court, to expeditiously search for and produce the documents that Pfizer requested, in exchange for Pfizer’s agreement to withdraw its motions to compel and for costs and fees.<sup>3</sup> Plaintiffs cannot reincarnate their relevance and burden objections months later.

Moreover, putting aside Plaintiffs’ unequivocal waiver of any burden objection that they may have had, Plaintiffs’ bald assertions through the unsworn and conclusory statements of their attorneys, in a brief, are simply insufficient to establish undue burden in this Court. “In order to demonstrate undue burden, the plaintiffs must provide affirmative proof in the form of affidavits or record evidence . . . the *ipse dixit* of counsel [ ] is not sufficient.” *See In re Sulfuric Acid Antitrust Litig.*, 231 F.R.D. 351, 360-61 (N.D. Ill. 2005). Further, Plaintiffs’ burden argument is based only on one Fund’s successful collection of certain medical records. Plaintiffs do not articulate, anywhere, any undue burden that would result from complying with any of Pfizer’s other discovery requests that do not relate to medical records collection. *See Schaap v. Executive Industries, Inc.*, 130 F.R.D. 384, 387 (N.D. Ill. 1990) (“[T]he objecting party must specify the

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<sup>3</sup> See 6/13/07 Tr. [D.E. 95] at 4-5.

nature of the burden and provide specific explanations . . . . The mere fact that [defendant] will be required to expend a considerable amount of time, effort, or expense in answering [requests] is not a sufficient reason to preclude discovery.”<sup>4</sup> Because Plaintiffs have failed to proffer any affidavit or record evidence as the case law requires, or otherwise explain how the vast majority of Pfizer’s requests would impose an undue burden on them, their objection should be rejected.<sup>5</sup>

Indeed, it is not surprising that no Fund employee has provided an affidavit demonstrating any undue burden that would result by complying with Pfizer’s discovery requests. The stated bases for Plaintiffs’ renewed burden objection – that they have to search the Internet for doctors’ addresses, make some telephone calls, review medical records to identify off-label prescriptions, and correspond with doctors to obtain records – all relate to tasks that Plaintiffs’ attorneys, legal assistants, or their retained health care professional will perform. The fact that Plaintiffs’ counsel may have to find some addresses, or send out letters, or review some documents, is not the kind of “undue burden” that is sufficient to deny Pfizer its right to conduct discovery in a case where Plaintiffs are seeking billions of dollars. These are simply routine aspects of the litigation process which Plaintiffs, unlike Pfizer, voluntarily initiated. “Of course, the effort required to produce the documents [Pfizer] seeks is not burden-free. But, that is not

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<sup>4</sup> See also *Eley v. Herman*, No. 1:04-cv-416, 2005 U.S. Dist. LEXIS 30476, at \*2-3 (N.D. Ind. Nov. 21, 2005) (a party claiming undue burden “must ‘adequately demonstrate the nature and extent of the claimed burden’ by making a ‘specific showing as to how disclosure of the requested documents and information would be particularly burdensome’”) (citation omitted).

<sup>5</sup> Plaintiffs’ single authority is clearly inapposite. In *Cohn v. Taco Bell Corp.*, No. 92-c-5852, 1993 WL 451463 (N.D. Ill. Nov. 1, 1993), the court found that the documents in question were “almost completely irrelevant” and a connection with the lawsuit “manifestly missing.” *Id.* at \*4. In contrast, the information that Pfizer seeks is directly related to Pfizer’s defenses and all elements of Plaintiffs’ claims. *Id.* at \*4. Pfizer’s requests are more analogous to that in *State Farm Mutual Automobile Insurance Co. v. CPT Medical Services, P.C.*, 375 F. Supp. 2d 141 (E.D.N.Y. 2005), where the district court affirmed an order compelling production of defendant physicians’ financial records, as well as information related to patients on which the physicians performed allegedly unnecessary tests, despite the plaintiff’s arguments with regard to confidentiality, and their conclusory allegations of undue burden. *Id.* at 156-57.

the test, or else there could be no discovery in any case. The question is whether the burden is an undue one.” *In re Sulfuric Acid*, 231 F.R.D. at 360. Here, there is no cognizable evidence in the record to support any undue burden objection by any Fund.<sup>6</sup>

Moreover, the lone example of “burden” that Plaintiffs describe is illusory, or at best, greatly exaggerated. In support of their undue burden objection, Plaintiffs assert that it was difficult and time-consuming to obtain records from doctors in Florida without sending a HIPAA-compliant authorization, and describe a few complications that obviously resulted from their own failure to follow the basic protocol of medical records collection in a post-HIPAA world by providing patient authorizations.<sup>7</sup> Nonetheless, even without an authorization and an agreed form letter, Plaintiffs admit that they were able to perform the task within a few weeks. The parties have now worked out and presented to the Court an agreed letter to physicians that will accompany a valid authorization from Fund participants, and this procedure will greatly facilitate the records retrieval process. *See* 8/24/07 email chain between S. Grygiel and M. Cheffo (attached as Ex. 1). With a proper authorization, and the agreed form letter, all of Plaintiffs’ concerns about HIPAA and administrative difficulties will be resolved.

## **II. PFIZER’S DOCUMENT REQUESTS REMAIN RELEVANT TO PLAINTIFFS’ LIABILITY, CAUSATION, AND DAMAGES CLAIMS**

“As an objecting party, [Plaintiffs are] required to specifically detail the reasons why *each* [request] is irrelevant – whether it be by a simple affidavit or some other evidence which

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<sup>6</sup> To be sure, Plaintiffs have had ample time to provide such evidence. Counsel for the parties conferred just after the motions to modify and compel were filed and agreed that the parties should establish a briefing schedule to avoid any last minute surprise filings, give each side ample opportunity to prepare its submissions, and provide this Court sufficient time to prepare for the hearing. Both sides’ reply papers are due at 4:00 PM on September 21, 2007, and the motions will be fully submitted at that time.

<sup>7</sup> As the Court will recall, Plaintiffs’ progress was also impeded by their failure to take any steps to respond to Pfizer’s discovery requests, or this Court’s Order, until two weeks before their deadline.

supports [their] objection.” *Schaap*, 130 F.R.D. at 386 (emphasis added). Plaintiffs’ opposition falls far short of this standard. Rather than articulate the basis for their objection to each request, Plaintiffs simply pronounce, in one broad stroke, that Pfizer’s seventy-one outstanding document requests are “related[ed] to Plaintiffs’ no longer operative complaint and are irrelevant to Plaintiffs’ Second Amended Complaint.”<sup>8</sup> Pls.’ Opp. at 1. Plaintiffs apparently believe that it is this Court’s job to dissect their eighty-five-page SAC to determine if any of Pfizer’s requests are no longer relevant.

#### **A. Plaintiffs’ SAC Actually Expands the Scope of Relevant Discovery**

Plaintiffs repeatedly claim that they “have amended their theory – expressly to narrow the scope of relevant information . . .” Pls.’ Opp. at 8.<sup>9</sup> Unfortunately, like so many other unqualified statements in Plaintiffs’ Motion to Modify and in the present opposition, it is simply not true. What Plaintiffs have done in their SAC is to retain the claims of the FAC and add additional claims that Pfizer failed to disclose various serious health risks, that the FDA wrongfully approved Lipitor for women and the elderly, and that Pfizer made inaccurate superiority claims about Lipitor. According to Plaintiffs, if all of the health risks were disclosed, or if the allegedly inaccurate superiority claims were never made, the price for Lipitor would have been less. However, simply making the allegations does not make them true. To the extent that Plaintiffs’ claims survive a motion to dismiss, the fact and expert discovery that will be

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<sup>8</sup> Interestingly, Plaintiffs’ argument that the SAC has mooted the majority of Pfizer’s prior discovery as irrelevant only seems to apply to Pfizer’s discovery to Plaintiffs, and not to Plaintiffs’ discovery to Pfizer.

<sup>9</sup> Despite Plaintiffs’ claims of streamlining the case, they have not supplemented their Rule 26 disclosures. Thus, Plaintiffs’ operative disclosure contains their initial damages calculation, and the same 340 witnesses, most of whom relate to the improper off-label marketing claims in the FAC and SAC.

required to establish or refute their new claims will be substantial, and will squarely implicate the FDA's role and jurisdiction.

For example, Plaintiffs repeatedly assert in support of their new fraudulent and negligent misrepresentation claims that Pfizer was allegedly "hiding or downplaying" certain "side effects and negative information" related to Lipitor. SAC ¶¶ 111, 190, 226. Given those allegations, Pfizer's discovery requests aimed at obtaining, for example, documents received by the Funds from Pfizer or any PBM regarding Lipitor (*see* Ex. A to Pfizer's Motion to Compel [D.E. 133], No. 2), Lipitor documents provided to plan participants (*id.*, Nos. 3 & 4), and documents containing statements about Lipitor relied upon by the Funds (*id.*, Nos. 29 & 30) or their participants (*id.*, No. 33), all remain highly relevant. Plaintiffs' new claims that Lipitor was improperly marketed to women and the elderly (*see* SAC ¶¶ 4, 25, 101-04), despite the FDA's approval for these groups, will also be discovery-intensive.<sup>10</sup> Accordingly, rather than "streamline" the case, the SAC adds a number of ill-defined, medically unsupportable, and speculative claims that will, if permitted to proceed, require significant discovery to debunk.

#### **B. Pfizer's Discovery Is Directly Relevant to Defending Against Plaintiffs' Claims**

In order to evaluate the merits of Plaintiffs' claims, and to prepare Pfizer's defenses, Pfizer is entitled to conduct discovery to establish that: (i) nothing about its marketing campaign was fraudulent or improper; (ii) the Funds did not pay for any improper off-label Lipitor prescriptions; and (iii) no physician who prescribed Lipitor for any Fund participants did so

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<sup>10</sup> This same claim was made several years ago in a federal case in the Southern District of Florida. As a result of three recent rulings by Judge Jordan, only a sliver of the original case has not yet been dismissed. *See Prohias v. Pfizer, Inc.*, 485 F. Supp. 2d 1329 (S.D. Fla. 2007); *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228 (S.D. Fla. 2007); *Prohias v. Pfizer, Inc.*, No. 05-22658, slip. op. (S.D. Fla. Aug. 15, 2007).

because of Pfizer's purportedly fraudulent marketing campaign.<sup>11</sup> Pfizer remains entitled to the discovery that this Court has already ruled is relevant, and that remains relevant under the SAC.

For example, the SAC alleges:

Fully informed pharmacy benefit managers and third party payors, among others, would have not bought Lipitor at all, or would have declined to buy it until Lipitor prices were lowered to reflect its many and potentially devastating side effects, and to reflect the truth that Lipitor was not materially safer than or superior to other statins. . . . PBMs and third-party payors would not have continued to pay full price for Lipitor had they known the drug was not the wonder drug Pfizer marketed it to be, was not materially more efficacious than other, cheaper statins at many dose levels, and even carried with it the seeds of potential destruction.

SAC ¶ 98; *see also id.* ¶ 125. Many of Pfizer's purportedly "irrelevant" discovery requests seek information critical to Pfizer's exploration of these allegations.<sup>12</sup> Additionally, the SAC alleges:

Pfizer's two-pronged scheme focused on expanding the number of patients taking Lipitor generally, by hiding or downplaying side effects and negative information and by falsely touting Lipitor's superior safety, efficacy and cost-effectiveness over competing statins. Pfizer's second prong specifically focused on expanding the Lipitor patient market beyond what ATP III and the Label recommend, through off-label marketing. ATP III guidelines recommend that patients with multiple risk factors and less than a 10% risk of developing CHD over the next 10 years may be considered for drug therapy only if their LDL level is 160 ml/dL or higher. For patients with an LDL between 130 ml/dL and 159 ml/dL, the ATP

<sup>11</sup> Rather, evidence will show that physicians prescribed Lipitor because, in their informed medical judgment, it was the best way of managing a particular patient's elevated cholesterol. That "evidence" – testimony from prescribing physicians – is not only relevant, it is at the very heart of this lawsuit, and Pfizer must be allowed access to it. That evidence would include not only the names of each of the prescribing physicians, but also their patient's medical records.

<sup>12</sup> *See, e.g.,* Ex. A to Pfizer's Motion to Compel, No. 2 (documents received from Pfizer or any PBM regarding Lipitor); No. 11 (contracts between Fund and any PBM for the last ten years); No. 16 (documents regarding PBM practices/procedures with respect to Lipitor); No. 17 (documents regarding Fund's decision to include Lipitor on formulary); No. 18 (documents regarding the possible removal of Lipitor from formulary); No. 19 (documents regarding Fund's initial determination to pay for Lipitor); No. 20 (documents reflecting any change in Fund's policy/practices/rules regarding Lipitor); No. 29 (documents containing any statement about Lipitor relied upon by Fund); No. 30 (any Lipitor ad or promotional piece relied upon by Fund); No. 31 (communications between Fund and PBMs regarding benefits provided); No. 53 (contracts between Fund and any entity providing assistance or consulting with regard to its PBM); No. 64 (reports provided by any consultant to trustees of Fund); No. 65 (documents from PBM identifying prescription medicines added to/removed from formulary).

III guidelines recommend only TLC. Nonetheless, Pfizer illegally promotes the drug for use in this patient population.

SAC ¶ 111; *see also id.* ¶¶ 112-13. Plaintiffs, therefore, cannot credibly argue that their assertions regarding Pfizer's alleged off-label promotion are no longer at issue.<sup>13</sup>

In fact, Plaintiffs state on the first page of their opposition, "[t]o the degree that off-label prescriptions factor into Plaintiffs' claims and damages, Plaintiffs will put forth expert economic and statistical evidence using an approach accepted by other courts in similar situations." Pls.' Opp. at 1. Translated, Plaintiffs are saying that we will indeed rely on off-label prescription information in connection with our liability and damages claims, and we will proffer some undisclosed statistical evidence at some undisclosed time using that off-label information, but we will not disclose during discovery any of the evidence or data that we intend to rely on and Pfizer is not entitled to conduct discovery about any of the off-label prescriptions that we claim to have paid for, but have yet to identify. Plaintiffs' position is untenable. Pfizer's right to obtain relevant discovery is certainly not limited to Plaintiffs' theory of damages or to "disput[ing] Plaintiffs' statistical analysis of data."<sup>14</sup> Pls.' Opp. at 10. *See, e.g., In re ATM Fee Antitrust Litig.*, No. C 04-02676, 2007 U.S. Dist. LEXIS 47943, at \*14 (N.D. Cal. June 25, 2007) (noting that the

<sup>13</sup> *See id.*, No. 7 (documents identifying any physician who prescribed Lipitor to a participant for an off-label purpose, as defined in the Amended Complaint); No. 9 (documents reflecting payments made for off-label Lipitor prescriptions); No. 23 (documents sufficient to identify the LDL level of each participant who received an off-label Lipitor prescription); No. 24 (documents sufficient to identify the ten-year cardiac risk profile for same); No. 33 (any Pfizer ad relied upon by any participant who filled an off-label Lipitor prescription); No. 34 (documents supporting the position that the NCEP Guidelines limit the Lipitor indication); No. 46 (copy of each Lipitor prescription paid for by Fund that was made for an off-label purpose); No. 47 (documents submitted by healthcare providers regarding off-label Lipitor prescriptions); No. 68 (documents identifying off-label participants' LDL, HDL, and triglyceride levels); No. 71 (documents sufficient to determine that each allegedly off-label Lipitor prescription was written for a person who was a member of the class to which the plan pertains).

<sup>14</sup> Neither *Klay v. Humana, Inc.*, 382 F.3d 1241 (11th Cir. 2004) nor *In re Neurontin*, No. 04-10981, 2007 WL 2437954 (D. Mass. Aug. 29, 2007), on which Plaintiffs rely (Pls.' Opp. at 6), support their position that Pfizer's discovery rights should be constrained by Plaintiffs' proposed damages methodology.

scope of discovery is defined by “the specific subject matter presented by Plaintiffs’ complaint” and “is not limited to [one party’s] theory of the case”).

### **III. PFIZER IS ENTITLED TO UNREDACTED PRESCRIPTION RECORDS, MEDICAL RECORDS, AND DOCUMENTS RELATING TO PLAINTIFFS’ IDENTIFICATION OF ANY IMPROPER OFF-LABEL PRESCRIPTIONS**

#### **A. Plaintiffs’ Indiscriminate Redaction of Participant Information Is Improper**

Plaintiffs fail to disclose that two of the Funds have produced un-redacted participant and prescription information, making it difficult to understand how the other Funds can claim that it would be improper for them to do the same. Plaintiffs also ignore their prior concession that it would be “administratively” simple for the other Funds to provide the participant and prescription information. 6/13/07 Tr. at 34. After the initial production, the other Funds switched positions and have refused to provide the un-redacted information that Pfizer needs to evaluate whether any participant, from any Fund, actually received a Lipitor prescription for an off-label purpose. Plaintiffs make the wholly unsupported and irresponsible claim that “Pfizer seeks the identities of individual fund participants primarily to harass Plaintiffs in an attempt to short circuit this litigation.” Pls.’ Opp. at 8. They cite Pfizer’s service of document subpoenas on the six participants identified by the Plumbers and Pipefitters Fund as having received, or possibly having received, Lipitor for an off-label purpose, and state, without citation or support, “[u]nderstandably, these individual beneficiaries are reluctant to share these intimate details with Pfizer.” Pls.’ Opp. at 8.

Had the Funds conducted an ounce of due diligence with their participants or their prescribing physicians before filing their claims, or during the seventeen months this lawsuit has been pending, it would have become crystal clear to them that what their participants are concerned about is their insurers’ efforts to: (i) curtail their access to medicines such as Lipitor, which they need and rely upon; and (ii) belittle the integrity and judgment of their physicians by

claiming that they prescribe medicines unnecessarily based on marketing versus sound medicine. Indeed, one of the participants identified by Plumbers and Pipefitters in response to Pfizer's request for participants who received an off-label Lipitor prescription, provided a voluntary statement indicating that she continues to take Lipitor, that her father and brother died of heart attacks, and that she was a smoker for twenty-eight years, is overweight and "pre-diabetic," and has a thyroid condition, and high cholesterol and tryglycerides. *See* Statement of Participant No. 6 (attached hereto as Ex. 2). She concluded: "I believe that my doctor prescribed Lipitor for me because he determined that it was in my best interest to take the medicine based on my cholesterol levels, family history and other health characteristics." *Id.*<sup>15</sup>

**B. Plaintiffs' Arguments That They Do Not Maintain, or Have the Right to Obtain, Certain Documents Are Unavailing**

Plaintiffs have not met their burden of establishing that the prescription and medical information and documents Pfizer has requested are not in their care, custody, or control. Plaintiffs themselves recognize that the term "control" "is to be liberally construed," and includes "the legal right to obtain the documents requested upon demand." Pls.' Opp. at 3 (quoting *Modern Eng'g. Inc. v. Peterson*, No. 07-CV-1055, 2007 WL 2680563, at \*3 (C.D. Ill. July 16, 2007)). Plaintiffs' own discovery responses contradict their conclusory assertion that "for many Funds 'control'," under this definition, "either does not exist or is, at best, unclear." *Id.* at 4. A number of the Funds have represented in their responses to requests for admission both that they maintain medical records for participants and that they receive medical records concerning participants in connection with their payment or reimbursement for pharmacy

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<sup>15</sup> Another participant who received a subpoena was eager to provide records supporting his cardiologist's decision to prescribe Lipitor for him after he underwent a cardiac procedure. The other four participants simply indicated that they did not have any responsive records, and did not make any complaints about any "harassing litigation tactics." Pls.' Opp. at 9.

benefits.<sup>16</sup> In addition, plan documents and contracts produced by those Funds who have actually provided such documents confirm that they have the right to obtain and use their participants' medical information for a number of purposes, including to adjudicate claims and in connection with a lawsuit or pursuant to a court order.<sup>17</sup>

As Pfizer has previously demonstrated, Plaintiffs' objections on privacy grounds are also meritless. *See* Pfizer's Opp. to Pls.' Motion to Modify Discovery [D.E. 139] at 11-12. It is well settled that parties are entitled to obtain relevant non-party medical records during discovery where, as here, the court has entered a HIPAA-compliant protective order. *See, e.g., U.S. v. Camillo*, 233 F.R.D. 520, 522 (S.D. Ill. 2005) ("HIPAA permits protected health information to be revealed in response to a discovery request, if the parties . . . have asked the Court for a protective order.").<sup>18</sup> Contrary to Plaintiffs' half-hearted argument that they would be unable to obtain records in states with disclosure rules that are more restrictive than HIPAA (Pls.' Opp. at 3-4),<sup>19</sup> the Seventh Circuit and other courts have expressly held that "in a federal question suit," such as the instant federal RICO action (*see* SAC ¶ 22), "state privacy and privilege laws do not

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<sup>16</sup> *See, e.g.*, First Amended and Supplemental Responses and Objections to Defendant Pfizer Inc.'s First Request for Admission to Plaintiff Teamsters Local Union 863 (attached as Ex. 3), Nos. 8-9. Plaintiffs Plumbers and Pipefitters, Electrical Workers Benefit Trust Fund, Laborers' District Council Building and Construction Health and Welfare Fund, and Laborers' District Council Heavy and Highway Utility Health and Welfare Fund provided the same responses to Requests Nos. 8 and 9. Cleveland Bakers has also indicated, in response to Request No. 8 that it maintains medical records for its participants.

<sup>17</sup> *See, e.g.*, Cleveland Bakers Notice of Privacy Practices (attached as Ex. 4); IBEW-NECA Notice of Privacy Policy, *available at* <http://www.neca-ibew.org/welfare/NoticePrivacyPolicy.pdf> (attached as Ex. 5); Midwestern Teamsters 2005 Summary Plan, Use and Disclosure of Your Protected Health Information (attached as Ex. 6); Southern Illinois Laborers 2005 Summary Plan, Privacy Amendment (attached as Ex. 7).

<sup>18</sup> *Accord Ligas v. Maram*, No. 05 C 4331, 2007 U.S. Dist. LEXIS 58911, at \*19 (N.D. Ill. Aug. 10, 2007); *State Farm Mutual Auto. Ins. Co. v. Accurate Med., P.C.*, CV 2007-0051, 2007 U.S. Dist. LEXIS 34410, at \*2-4 (E.D.N.Y. May 10, 2007).

<sup>19</sup> Plaintiffs did not raise any state law issues during the parties' negotiation of the protective order and have not challenged Pfizer's requests under any specific state law provisions.

apply, regardless of whether the state law might be more restrictive than the applicable federal rule.” *Ligas*, 2007 U.S. Dist. LEXIS 58911, at \*20 (citing *Northwestern Mem. Hosp. v. Ashcroft*, 362 F.3d 923, 925 (7th Cir. 2004)); accord *Camillo*, 233 F.R.D. at 522-23; *Accurate Med.*, 2007 U.S. Dist. LEXIS 34410, at \*2-3.<sup>20</sup>

#### IV. PLAINTIFFS MUST PROVIDE INFORMATION ABOUT THE SOURCE OF THE INTERNAL DOCUMENTS THEY REFERENCED AND PRODUCED

Plaintiffs do not dispute the relevance or targeted scope of Pfizer’s single interrogatory seeking factual information about the source of and circumstances under which they obtained over 2,200 pages and several CDs and videotapes of confidential and proprietary, and apparently misappropriated, Pfizer materials that they have referenced and relied upon in all three of their complaints and produced to Pfizer during discovery. In fact, each of the Funds has admitted that it possesses an identical set of the documents. For the first time, Plaintiffs have now cryptically claimed that the documents are somehow related to a pre-filing interview and therefore any questions about how the Funds got the documents, whether they relied on them, who saw them, or if they caused a change of conduct, are protected by work product. But Plaintiffs’ paper thin work product objection has been rejected by courts in this District and throughout the country.

Plaintiffs have not met their burden of establishing that the work product doctrine even applies to the information they refuse to disclose. See *Christman v. Brauvn Realty Advisors, Inc.*, 185 F.R.D. 251, 256 (N.D. Ill. 1999). They assert only that they “should not be required to identify individuals interviewed as part of a pre-suit investigation” (Pls.’ Opp. at 12), but

have made no showing that discovery of the names of the persons [from whom they obtained the documents] would provide any insight into Plaintiffs’ counsel’s litigation strategy. Moreover, Plaintiffs have already revealed through their

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<sup>20</sup> Moreover, Plaintiffs have agreed to a form letter to physicians that would enclose an authorization form executed by the participant.

allegations what information was provided by the witnesses whose identity [Pfizer] seek[s] in this motion.

*In re Theragenics Corp. Secs. Litig.*, 205 F.R.D. 631, 636 (N.D. Ga. 2002) (ordering plaintiffs to disclose the names of individuals upon whom they relied in making allegations in their complaint); *see also Am. Floral Servs., Inc. v. Florists' Transworld Delivery Assoc.*, 107 F.R.D. 258, 261 (N.D. Ill. 1985) ("Of course [defendant] already knows the nature of [plaintiff's] claim, and the mere identification of persons who know facts bearing on that claim tells [defendant] nothing new about the mental processes of [plaintiff's] lawyers."). As these and many other courts have held, the work product doctrine does not shield factual information that a plaintiff has about its case, including the "identity of witnesses having knowledge of relevant facts." *Am. Floral Servs.*, 107 F.R.D. at 260; *accord Stewart v. Gen. Motors Corp.*, No. 86 C 4741, 1998 U.S. Dist. LEXIS 598, at \*12 (N.D. Ill. Jan. 26, 1998) (the work product doctrine does not protect "information about sources of information, who has worked on the documents, and who has possessed the documents"); *see also In re Theragenics Corp. Secs. Litig.*, 205 F.R.D. at 634 ("Numerous courts since *Hickman v. Taylor* [329 U.S. 495, 511 (1947)] have recognized that names and addresses of witnesses interviewed by counsel who have knowledge of the facts alleged in the complaint are not protected from disclosure by the work product doctrine."); *Brody v. Zix Corp.*, No. 3-04-CV-1931, 2007 U.S. Dist. LEXIS 38230, at \*5 (N.D. Tex. May 25, 2007) (following multiple authorities finding that "the work product doctrine does not shield from discovery the identity of persons with knowledge of relevant facts, even if such persons serve as confidential sources during the course of a pre-suit investigation").<sup>21</sup>

<sup>21</sup> The only two cases on which Plaintiffs rely for their argument that the disclosure of "the identity of witnesses interviewed in pre-suit investigation" somehow "reveals attorney mental impressions and trial strategy" (Pls.' Opp. at 12) – *In re MTI Technology Corporate Securities Litigation*, No. SACV 00-0745, 2002 WL 32344347 (C.D. Cal. June 13, 2002) and *In re Ashworth, Inc. Securities Litigation*, No.

(cont'd)

In sum, neither the discovery rules nor the work product doctrine support Plaintiffs' effort to prejudice Pfizer by denying it the right to discover facts about Plaintiffs' acquisition of internal Pfizer materials. Pfizer is plainly entitled to prepare its defense by, among other things, deposing the fact witness(es) from whom Plaintiffs obtained those materials. Accordingly, Plaintiffs should be compelled to respond to Pfizer's interrogatory.

### CONCLUSION

For the foregoing reasons, and the reasons set forth in Pfizer's opening memorandum, Pfizer respectfully requests that the Court grant Pfizer's motion to compel and any further relief that the Court deems just and proper.

DATED: September 21, 2007

Respectfully submitted,

**PFIZER INC**

By its attorneys,

/s/Andrew J. Jarzyna  
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Counsel for Defendant Pfizer Inc

*(cont'd from previous page)*

99cv0121, 213 F.R.D. 385 (S.D. Cal. Aug. 6, 2002) – have been expressly rejected by the overwhelming majority of courts that have considered the issue, including other California courts. *See, e.g., In re Harmonic, Inc. Secs. Litig.*, No. C-00-2287, 2007 U.S. Dist. LEXIS 68351, at \*12-17 (N.D. Cal. Sept. 13, 2007); *Miller v. Ventro Corp.*, No. C01-01287, 2004 WL 868202, at \*2 (N.D. Cal. Apr. 21, 2007); *see also Brody*, 2007 U.S. Dist. LEXIS 38230, at \*5-6; *Norflet v. John Hancock Fin. Servs., Inc.*, No. 3:04cv1099, 2007 U.S. Dist. LEXIS 8410, at \*8-10 (D. Conn. Feb. 5, 2007). Moreover, neither *MTI Technology* nor *In re Ashworth* involved a request, like Pfizer's, for factual information about the source of documents that Plaintiffs have directly referenced in their pleadings and produced during discovery.

*-Of Counsel-*

Barbara Wrubel  
Mark S. Cheffo  
Hayden A. Coleman  
SKADDEN, ARPS, SLATE,  
MEAGHER & FLOM LLP  
Four Times Square  
New York, New York 10036  
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### **CERTIFICATE OF SERVICE**

I, Andrew J. Jarzyna, an attorney, certify that on this 21st day of September, 2007, one true and correct copy of the foregoing Reply In Further Support of Pfizer's Motion to Compel was served through this Court's electronic filing system upon the following counsel for Plaintiffs: George S. Bellas, gsb@cliffordlaw.com; Robert A. Clifford, rac@cliffordlaw.com; Sidney S. Liebesman, sliebesman@gelaw.com; Patrick J. O'Hara, patrick@cavanagh-ohara.com; and Thomas K Prindable, tkp@cliffordlaw.com.

/s/Andrew J. Jarzyna  
Andrew J. Jarzyna

## **EXHIBIT 1**

From: Steve Grygiel [mailto:SGrygiel@gelaw.com]  
Sent: Friday, August 24, 2007 4:22 PM  
To: Cheffo, Mark  
Cc: Jarzyna, Andrew  
Subject: RE: SIL

Mark,

As we discussed today, this e-mail follows up on one portion of our teleconference of this afternoon, memorializing the Plaintiffs' position on Pfizer's proposed records request letter:

1. The text of the proposed letter, as far as it goes, is acceptable.
2. Plaintiffs believe they should also have the ability to seek records without patient authorization, with Pfizer's proposed letter modified accordingly. (You address this in 2d para. of your email.)
3. Plaintiffs generally do not agree that Pfizer should be able to control or influence how Plaintiffs communicate to doctors about getting Fund participant records. However, as we discussed, the Court ordered Pfizer to propose a draft, Pfizer did, and we are both seeking to comply with the Court's order to meet and confer on the issue.

Thank you - we will talk before Tuesday by email, most likely, as we discussed today.

Steve

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From: Cheffo, Mark [mailto:MCHEFFO@skadden.com]  
Sent: Friday, August 17, 2007 7:13 PM  
To: Steve Grygiel  
Cc: Jarzyna, Andrew  
Subject: SIL

Steve,

As the Court directed, attached please find a proposed letter that the other Funds can send to physicians to obtain medical records. As you will note, we think the best, most effective, and least controversial approach is simply to get authorizations from your clients' own participants since they have ready access to them and the Funds have a contractual right to the participants' cooperation. Also, our proposed letter and authorization approach remedies the HIPAA problems raised by the letter that the P and P Fund sent out.

To the extent that the Fund cannot obtain an authorization from a participant in a specific instance, we can discuss a letter to the provider that reflects that situation and fairly explains that the Fund needs medical records to which it is entitled under the Plan.

Please let me know what you think.

Mark

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Dear Doctor,

Plumbers & Pipefitters provides, among other benefits, health care and prescription drug coverage to its members. We are writing in connection with your patient [insert patient name], who is a participant in our fund. Attached herewith, please find an executed HIPAA compliant authorization for the release of [insert patient name]'s medical records.

Pursuant to this authorization, we request that you provide us with a copy of records relating to [insert patient name]. Please forward all records, including, but not limited to, records, reports, complete charts, diagnostic tests of any kind, films, x-rays, MRIs, CT Scans, notes, medical reports, laboratory records and reports, pathology records, pharmacy records, physical therapy records, nurses' notes/reports, patient questionnaires or information sheets, discharge summaries, operative reports, order sheets, hematology records, billing and payment records, the names of other physicians consulted or to whom the patient was referred, and any and all correspondence relating to [insert patient name].

Please advise us of any cost in connection with this request and a check will be forwarded to you promptly. Please address all correspondence in this matter to my attention. Thank you in advance for your assistance.

As you will note, we have copied [insert patient name] on this request.

Sincerely,

XX

Cc: [insert patient name]

\*\*\*\*\*

This email and any attachments thereto, is intended only for use by the addressee(s) named herein and may contain legally privileged and/or confidential information. If you are not the intended recipient of this email, you are hereby notified any dissemination, distribution or copying of this email, and any attachments thereto, is strictly prohibited. If you receive this email in error please immediately notify me at (212) 735-3000 and permanently delete the original copy and any copy of any email, and any printout thereof.

Further information about the firm, a list of the Partners and their professional qualifications will be provided upon request.

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To ensure compliance with Treasury Department regulations, we advise you that, unless otherwise expressly indicated, any federal tax advice contained in this message was not intended or written to be used, and cannot be used, for the purpose of (i) avoiding tax-related penalties under the Internal Revenue Code or applicable state or local tax law provisions or (ii) promoting, marketing or recommending to another party any tax-related matters addressed herein.

\*\*\*\*\*

This e-mail and any attachments thereto, is intended only for use by the addressee(s) named herein and may contain legally privileged and/or confidential information. If you are not the intended recipient of this e-mail, you are hereby notified any dissemination, distribution or copying of this email, and any attachments thereto, is strictly prohibited. If you receive this email in error please immediately notify me at (212) 735-3000 and permanently delete the original copy and any copy of any e-mail, and any printout thereof.

Further information about the firm, a list of the Partners and their professional qualifications will be provided upon request.

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## **EXHIBIT 2**

1. I am 57 years old, and reside at

Redacted

Redacted

2. On August 31, 2007, I received a subpoena asking me to provide certain documents to attorneys for Pfizer, in connection with a lawsuit brought by Plumbers and Pipefitters Local Union 630 Welfare Trust Fund.

3. I contacted Mark Cheffo on September 5, 2007, at the telephone number included on the subpoena, and he returned my call that evening.

4. During our call, I advised Mr. Cheffo that I had not been told about the lawsuit, had not been asked by anyone to sign any authorization for the release of my medical records, and that I was not aware that the Fund had obtained some of my medical records.

5. I also advised Mr. Cheffo that my physician prescribed Lipitor for me and that I continue to take the medicine and pay \$40.00 as a co-pay because it is a branded medicine, as opposed to a \$20.00 co-pay for generic medicines.

6. I told Mr. Cheffo that I smoked cigarettes for approximately 28 years, and that despite my efforts to lose weight, I am overweight. I stated that my brother died at age 42 of a heart attack, and that my father also died of a heart attack. I have high blood pressure that I control with a prescription medicine, I have a thyroid condition, high cholesterol, high triglycerides, sleep apnea and I have been told by a health care professional that I am "pre-diabetic."

7. I believe that my doctor prescribed Lipitor for me because he determined that it was in my best interest to take the medicine based on my cholesterol levels, family history, and other health characteristics.

I have read the above paragraphs and they are true, and fairly and accurately represent what I told Mark Cheffo on September 5, 2007.

Signature Redacted

## **EXHIBIT 3**

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

SOUTHERN ILLINOIS LABORERS' AND )  
EMPLOYERS' HEALTH AND WELFARE )  
FUND; NECA-IBEW WELFARE TRUST )  
FUND; MIDWESTERN TEAMSTERS )  
HEALTH AND WELFARE FUND; THE )  
WELFARE FUND OF TEAMSTERS )  
LOCAL UNION 863; PLUMBERS AND )  
PIPEFITTERS LOCAL UNION 630 )  
WELFARE TRUST FUND; CLEVELAND )  
BAKERS AND TEAMSTERS HEALTH )  
AND WELFARE FUND; ELECTRICAL )  
WORKERS BENEFIT TRUST FUND; FIRE )  
& POLICE RETIREE HEALTH CARE )  
FUND, SAN ANTONIO; LABORERS' )  
DISTRICT COUNCIL BUILDING AND )  
CONSTRUCTION HEALTH AND )  
WELFARE FUND; LABORERS' )  
DISTRICT COUNCIL HEAVY AND )  
HIGHWAY UTILITY HEALTH AND )  
WELFARE FUND; NEW YORK CITY )  
POLICE SERGEANTS BENEVOLENT )  
ASSOCIATION HEALTH & WELFARE )  
FUNDS; and SIDNEY HILLMAN HEALTH )  
CENTER OF ROCHESTER, individually, )  
and on behalf of all others similarly situated, )

Plaintiffs, )

v. )

PFIZER INC., )

Defendant. )

No. 06CV1818

JUDGE JOHN W. DARRAH

MAGISTRATE JUDGE  
GERALDINE SOAT BROWN

**FIRST AMENDED AND SUPPLEMENTAL RESPONSES AND  
OBJECTIONS TO DEFENDANT PFIZER INC.'S FIRST REQUEST  
FOR ADMISSION TO PLAINTIFF TEAMSTERS LOCAL  
UNION 863 DATED DECEMBER 15, 2006**

Pursuant to Federal Rule of Civil Procedure 36, Plaintiff Welfare Fund of Teamsters Local Union 863 ("Local 863 Fund") hereby responds to Defendant Pfizer Inc.'s First Requests for Admission to Plaintiff (the "Requests"). This amended and supplemented response supersedes all prior responses to the Requests.

### **GENERAL OBJECTIONS**

1. Plaintiff objects to the Requests insofar as providing a response would divulge information: (i) prepared in anticipation of litigation; (ii) that constitutes privileged attorney-client materials; (iii) that constitutes protected work product; or (iv) that otherwise is protected from disclosure under any applicable statutory, constitutional or common law principle.

2. Plaintiff objects to the Requests to the extent that they: (i) seek information and/or materials beyond the scope of discovery as provided for in the Federal Rules of Civil Procedure; and/or (ii) otherwise may be construed to require responses beyond those required by any applicable laws.

3. Plaintiff objects to the Requests to the extent that they are overly broad, irrelevant, are not limited to the subject matter of this litigation or of any claim or defense of any party hereto, are not reasonably calculated to lead to the discovery of admissible evidence, and/or are unduly burdensome.

4. Plaintiff will respond to the Requests subject to, without intending to waive, and expressly reserving the right at any time to revise, correct, amend, supplement or clarify any of the responses or objections herein.

5. In responding to the Requests, Plaintiff neither waives nor intends to waive, but expressly reserves, any and all objections as to the authenticity, relevance, competency,

materiality or admissibility of any information or documents produced, set forth, identified or referred to herein.

**SPECIFIC RESPONSES AND OBJECTIONS  
TO REQUESTS FOR ADMISSION**

Each of the foregoing general objections is expressly incorporated into each of the specific responses set forth below as if they were fully repeated in each such response.

**RESPONSES TO REQUESTS FOR ADMISSION**

**REQUEST NO. 1:**

Please admit that your participants reside primarily in New Jersey.

**RESPONSE TO REQUEST NO. 1:**

Plaintiff admits this request.

**REQUEST TO NO. 2:**

Please admit that the majority of physicians who provide medical services for your participants maintain an office in New Jersey.

**RESPONSE TO REQUEST 2:**

Plaintiff admits this request.

**REQUEST NO. 3:**

Please admit that you are headquartered in New Jersey.

**RESPONSE TO REQUEST 3:**

Plaintiff admits this request.

**REQUEST NO. 4**

Please admit that documents pertaining to the administration and operation of your Plan are maintained primarily in New Jersey.

**RESPONSE TO REQUEST NO. 4:**

Plaintiff admits this request.

**REQUEST NO. 5:**

Please admit that a majority of your officers and directors reside in New Jersey.

**RESPONSE TO REQUEST NO. 5:**

Plaintiff admits this request.

**REQUEST NO. 6:**

Please admit that between January 1, 2002 and the date of your response, your business operations, including your communications with your pharmacy benefit manager ("PBM"), took place primarily in New Jersey.

**RESPONSE TO REQUEST NO. 6:**

Plaintiff admits this request.

**REQUEST NO. 7:**

Please admit that your outside consultants and advisors are located primarily in New Jersey.

**RESPONSE TO REQUEST NO. 7:**

Plaintiff, upon information and belief, admits that its outside consultants are located primarily in New Jersey. Plaintiff denies this request in all other respects.

**REQUEST NO. 8:**

Please admit that you do not maintain any medical records for your participants.

**RESPONSE TO REQUEST NO. 8:**

Plaintiff denies this request.

**REQUEST NO. 9:**

Please admit that you do not receive any medical records concerning your participants in connection with your reimbursement or payment for participant pharmacy benefits.

**RESPONSE TO REQUEST NO. 9:**

Plaintiff denies this request.

**REQUEST NO. 10:**

Please admit that you do not receive blood LDL levels for participants in the ordinary course of your business.

**RESPONSE TO REQUEST NO. 10:**

Plaintiff admits this request.

**REQUEST NO. 11:**

Please admit that you do not maintain blood LDL levels for participants.

**RESPONSE TO REQUEST NO. 11:**

Plaintiff admits this request.

**REQUEST NO. 12:**

Please admit that you do not have the documents referenced in the Amended Complaint.

**RESPONSE TO REQUEST NO. 12:**

Plaintiff denies this request.

**REQUEST NO. 13:**

Please admit that you have not, within the last two years, altered your procedures or guidelines regarding reimbursement or payment specifically for Lipitor.

**RESPONSE TO REQUEST NO. 13:**

Plaintiff admits this request.

**REQUEST NO. 14:**

Please admit that you have no contracts with Pfizer.

**RESPONSE TO REQUEST NO. 14:**

Plaintiff admits this request.

**REQUEST NO. 15:**

Please admit that you have not met with any employee of Pfizer regarding Lipitor.

**RESPONSE TO REQUEST NO. 15:**

Plaintiff admits this request.

**REQUEST NO. 16:**

Please admit that you have not communicated directly with any employee of Pfizer regarding Lipitor.

**RESPONSE TO REQUEST NO. 16:**

Plaintiff admits this request.

**REQUEST NO. 17:**

Please admit that you have not communicated about Lipitor with any PBM under contract with you.

**RESPONSE TO REQUEST NO. 17:**

Plaintiff denies this request.

**REQUEST NO. 18:**

Please admit that the decision to make Lipitor available to your participants was made by the PBM with whom you contracted.

**RESPONSE TO REQUEST NO. 18:**

Plaintiff admits this request.

**REQUEST NO. 19:**

Please admit that you do not know what your PBM was told about Lipitor by Pfizer or any of its agents.

**RESPONSE TO REQUEST NO. 19:**

Plaintiff admits this request.

**REQUEST NO. 20:**

Please admit that you have no knowledge about whether your PBM relied upon any statement by Pfizer or any of its agents concerning Lipitor.

**RESPONSE TO REQUEST NO. 20:**

Plaintiff admits this request.

**REQUEST NO. 21:**

Please admit that physicians may lawfully prescribe Lipitor for off-label uses.

**RESPONSE TO REQUEST NO. 21:**

Plaintiff admits this request.

**REQUEST NO. 22:**

Please admit that physicians may lawfully prescribe Lipitor for a patient with two or more risk factors for heart disease, an LDL level between 130-159 mg/dL, and ten year cardiac risk profile between 1-10%.

**RESPONSE TO REQUEST NO. 22:**

Plaintiff admits this request.

**REQUEST NO. 23:**

Please admit that you do not possess data or information sufficient to determine whether any Lipitor prescription written for any participant between January 1, 2002 and December 18, 2006, was written for an off-label purpose.

**RESPONSE TO REQUEST NO. 23:**

Plaintiff denies this request.

**REQUEST NO. 24:**

Please admit that you generally reimburse your participants for prescriptions given to them by their physicians if they are written for an off-label purpose.

**RESPONSE TO REQUEST NO. 24:**

Plaintiff denies this request.

**REQUEST NO. 25:**

Please admit that your employees, officers, and directors have not relied upon any Pfizer Lipitor advertisement, promotion, or statement in making reimbursement or payment decisions.

**RESPONSE TO REQUEST NO. 25:**

Plaintiff objects to this request to the extent it calls for a legal conclusion. Subject to the foregoing objection, Plaintiff admits that its employees, officers, and directors relied on Pfizer to market Lipitor in accordance with the law when making reimbursement or payment decisions.

Plaintiff denies this request in all other respects.

**REQUEST NO. 26:**

Please admit that your employees responsible for decisions regarding reimbursement or payment for Lipitor have never believed that Lipitor was approved for any use beyond those defined on its label.

**RESPONSE TO REQUEST NO. 26:**

Plaintiff denies this request.

**REQUEST NO. 27:**

Please admit that you continue to pay for Lipitor prescriptions for participants with two or more risk factors for heart disease, an LDL level between 130-159 mg/dL, and a ten year cardiac risk profile between 1-10%.

**RESPONSE TO REQUEST NO. 27:**

Plaintiff admits this request.

**REQUEST NO. 28:**

Please admit that under your rules and guidelines, your participants are permitted to fill a Lipitor prescription given to them by a licensed physician, without having to obtain any additional approval or authorization from you.

**RESPONSE TO REQUEST NO. 28:**

Plaintiff admits this request.

**REQUEST NO. 29:**

Please admit that you do not restrict a physician's ability to switch plan participants from another statin to Lipitor.

**RESPONSE TO REQUEST NO. 29:**

Plaintiff admits this request.

**REQUEST NO. 30:**

Please admit that you currently pay for Lipitor prescriptions for your participants without knowledge of the participants' LDL levels.

**RESPONSE TO REQUEST NO. 30:**

Plaintiff admits this request.

**REQUEST NO. 31:**

Please admit that your PBM does not require a participant or his or her physician to provide LDL levels before it fills a prescription for Lipitor.

**RESPONSE TO REQUEST NO. 31:**

Plaintiff admits this request.

**REQUEST NO. 32:**

Please admit that you do not seek damages for prescriptions filled by any participant who had his or her LDL cholesterol lowered below 160 mg/dL by another statin before being switched by his or her physician to Lipitor.

**RESPONSE TO REQUEST NO. 32:**

Plaintiff denies this request.

**REQUEST NO. 33:**

Please admit that your trust agreement provides that questions pertinent to the validity or construction of trust, or your acts and transactions, shall be determined in accordance with the laws of the State of New Jersey.

**RESPONSE TO REQUEST NO. 33:**

Plaintiff admits this request.

**REQUEST NO. 34:**

Please admit that you have not removed Lipitor from your formulary.

**RESPONSE TO REQUEST NO. 34:**

Plaintiff admits this request.

**REQUEST NO. 35:**

Please admit that you have not, within the last two years, adopted any limitations concerning the prescription of Lipitor to your participants.

**RESPONSE TO REQUEST NO. 35:**

Plaintiff admits this request.

**REQUEST NO. 36:**

Please admit that you do not claim that any of your participants sustained any personal injury as a result of using Lipitor.

**RESPONSE TO REQUEST NO. 36:**

In addition to the foregoing general objections, Plaintiff objects to this request as overly broad and unduly burdensome. Subject to the foregoing general and specific objections, Plaintiff admits that it is not seeking any damages in this lawsuit for any personal injuries sustained by any participants as a result of using Lipitor, but Plaintiff reserves the right to bring such claims to the extent that it is damaged by any such personal injuries. Plaintiff also reserves the right to rely on evidence of injuries and side effects resulting from the use of Lipitor to extent such evidence is relevant to its claims.

**REQUEST NO. 37:**

Please admit that you do not claim that Lipitor failed to regulate lipid levels for any participant using Lipitor.

**RESPONSE TO REQUEST NO. 37:**

In addition to the foregoing general objections, Plaintiff objects to this request as overly broad and unduly burdensome. Subject to the foregoing general and specific objections, Plaintiff admits that it is not seeking any damages in this lawsuit for any failure to regulate lipid levels for

participants using Lipitor, but Plaintiff reserves the right to bring such claims to the extent that it is damaged by Lipitor's failure to regulated lipid levels. Plaintiff also reserves the right to rely on evidence of injuries and side effects resulting from the use of Lipitor to extent such evidence is relevant to its claims.

**REQUEST NO. 38:**

Please admit that you encourage the reduction of LDL cholesterol levels for your participants in an effort to reduce their risk of heart disease, heart attacks and hospitalizations.

**RESPONSE TO REQUEST NO. 38:**

Plaintiff denies this request.

**REQUEST NO. 39:**

Please admit that no Lipitor prescription written for any of your participants was "medically necessary" as that term is defined in your summary plan documents.

**RESPONSE TO REQUEST NO. 39:**

Plaintiff denies this request.

**REQUEST NO. 40:**

Please admit that you can refuse to reimburse one of your participants for Lipitor purchased by him or her if you determine that the purchase did not comply with the terms of your Plan.

**RESPONSE TO REQUEST NO. 40:**

Plaintiff admits this request.

**REQUEST NO. 41:**

Please admit that any PBM under contract with you filled prescriptions for Lipitor for your participants during the class period without knowing the LDL levels of such participants.

**RESPONSE TO REQUEST NO. 41:**

Plaintiff admits this request.

**REQUEST NO. 42:**

Please admit that any PBM under contract with you filled prescriptions for Lipitor for your participants, during the class period, without knowing whether such participants had any risk factors for heart disease.

**RESPONSE TO REQUEST NO. 42:**

Plaintiff admits this request.

**REQUEST NO. 43:**

Please admit that any PBM under contract with you filled prescriptions for Lipitor for your participants during the class period, without knowing the ten year cardiac risk profile of such participants.

**RESPONSE TO REQUEST NO. 43:**

Plaintiff admits this request.

**REQUEST NO. 44:**

Please admit that the PBM under contract with you does not, as part of its business operations, make a determination about whether a Lipitor prescription filled by one of your participants was written for an off-label purpose.

**RESPONSE TO REQUEST NO. 44:**

Plaintiff admits this request.

**REQUEST NO. 45:**

Please admit that the PBM under contract with you does not possess sufficient information to determine whether a Lipitor prescription filled by one of your participants during the class period was written for an off-label purpose.

**RESPONSE TO REQUEST NO. 45:**

Plaintiff admits this request.

**REQUEST NO. 46:**

Please admit that you had no communications, prior to December 1, 2006, with the PBM under contract with you about removing Lipitor from your formulary.

**RESPONSE TO REQUEST NO. 46:**

Plaintiff admits this request.

**REQUEST NO. 47:**

Please admit that Lipitor is a preferred medicine on your formulary.

**RESPONSE TO REQUEST NO. 47:**

Plaintiff denies this request.

**REQUEST NO. 48:**

Please admit that you do not have any rules, requirements or guidelines that apply only to Lipitor, and not to any other medicines on your formulary.

**RESPONSE TO REQUEST NO. 48:**

Plaintiff admits this request.

**REQUEST NO. 49:**

Please admit that you are not seeking reimbursement from Pfizer for each and every Lipitor prescription reimbursed by you, and filled between January 1, 2002 and December 18, 2006 by one of your participants who had an LDL level between 130-159 mg/dL, two or more risk factors for heart disease, and a ten year cardiac heart risk of less than 10% (as referred to in the NCEP Guidelines).

**RESPONSE TO REQUEST NO. 49:**

Plaintiff denies this request.

**REQUEST NO. 50:**

Please admit that your rules and guidelines do not restrict reimbursement for medicines on your formulary prescribed for off-label purposes.

**RESPONSE TO REQUEST NO. 50:**

Plaintiff denies this request.

**REQUEST NO. 51:**

Please admit that you have not determined the identity of any participant who received a Lipitor prescription for an off-label purpose as that term is defined in the Amended Complaint.

**RESPONSE TO REQUEST NO. 51:**

Plaintiff admits this request.

**REQUEST NO. 52:**

Please admit that you have not identified any prescription for Lipitor filled by one of your participants that was written for an off-label purpose as that term is defined in the Amended Complaint.

**RESPONSE TO REQUEST NO. 52:**

Plaintiff admits this request.

**REQUEST NO. 53:**

Please admit that you have not identified any physician who wrote a Lipitor prescription for one of your participants for an off-label purpose as that term is defined in the Amended Complaint.

**RESPONSE TO REQUEST NO. 53:**

Plaintiff admits this request.

**REQUEST NO. 54:**

Please admit that you encourage your participants to consult with their physicians periodically about monitoring their LDL and total cholesterol levels.

**RESPONSE TO REQUEST NO. 54:**

Plaintiff denies this request.

**REQUEST NO. 55:**

Please admit that you advised your PBM, prior to December 1, 2006, that some of your participants had received Lipitor for an off-label purpose.

**RESPONSE TO REQUEST NO. 55:**

Plaintiff denies this request.

DATED: June 6, 2007

/s/ Stephen G. Grygiel  
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*Lead Counsel for Plaintiff and Proposed Lead  
Counsel for the Class*

**CERTIFICATE OF SERVICE**

I, Naumon A. Amjed, certify that on this 6<sup>th</sup> day of June, 2007, a true and correct copy of the foregoing amended discovery response was served by electronic mailing upon the following counsel for Defendant Pfizer Inc.:

Mark S. Cheffo, Esq.  
Skadden, Arps, Slate, Meagher & Flom LLP  
Four Times Square  
New York, NY 10036-6522  
Email: mcheffo@skadden.com

/s/ Naumon A. Amjed  
Naumon A. Amjed

## **EXHIBIT 4**

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## NOTICE OF PRIVACY PRACTICES

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**THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAYBE BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.**

### **EFFECTIVE DATE**

This Notice is effective April 14, 2003.

### **YOUR PRIVACY IS IMPORTANT TO US**

The Cleveland Bakers and Teamsters Health and Welfare Fund (the "Fund") has always been committed to protecting the information that you share with us and is required by law to maintain the privacy of your protected health information ("PHI"). The fund holds its employees and consultants to strict policies and procedures regarding the security of your information. This Notice of Privacy Practices will explain the type of information that we collect, how we use that information, how we protect that information, you rights as they relate to your information and our legal duties and privacy practices.

### **USE AND DISCLOSURE OF HEALTH INFORMATION**

The Cleveland Bakers and Teamsters Health and Welfare Fund's benefit plans (the "Plan") and its Business Associates may use your health information, that is information that constitutes protected health information as defined in the Privacy Rule of the Administrative Simplification provision of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), without authorization, consent or opportunity to agree or object for purposes of making or obtaining payment for your care and conducting health care operations. The Plan has amended its plan documents to protect your protected health information ("PHI") as required by HIPAA.. The Plan has established policies and procedures as well as administrative, technical and physical safeguards to prevent unnecessary disclosure of your health information.

**THE FOLLOWING IS A SUMMARY OF THE CIRCUMSTANCES UNDER WHICH AND PURPOSES FOR WHICH YOUR HEALTH INFORMATION MAY BE USED AND DISCLOSED:**

**To Make or Obtain Payment.** The Plan may use or disclose your health information to make payment to or collect payment from third parties, such as other health plans or providers, for the care you receive. For example, the Plan may provide information regarding your coverage or health care treatment to a health care provider to confirm your coverage at the time of treatment or to other health plans to coordinate payment of benefits.

**To Conduct Health Care Operations.** The Plan may use or disclose health information for it own operations of facilitate the administration of the Plan and as necessary to provide

coverage and services to all of the Plan's participants. Health care operations includes such activities as:

- Quality assessment and improvement activities.
- Activities designed to improve overall health or reduce health care costs, including disease management.
- Contacting health care providers and participants with information about treatment alternatives and other related functions.
- Review or evaluation of the competency or qualifications of health care professionals including performance evaluation.
- Accreditation, certification, licensing or credentialing activities.
- Underwriting, premium rating or related functions to create, renew or replace health insurance or health benefits under a health insurance contract.
- Clinical guideline and protocol development, case management and care coordination.
- Conducting or arranging for review or auditing functions, including compliance reviews, medical reviews, legal services, audit services, fraud and abuse detection programs, and compliance programs.
- Business planning and development including cost management and planning related analysis and formulary development.
- Business management and general administrative activities of the Plan, including customer service and resolution of internal grievances.

For example, the Plan may use your health information to conduct case management, quality improvement and utilization review, and provider credentialing activities or to engage in customer service and grievance resolution activities. In addition, we may use your health information to refer you to disease management or wellness programs, project future costs related to benefits or audit the accuracy of claims processing functions.

**For Treatment Alternatives/ Appointment Reminders.** The Plan may use and disclose Your health information to provide information to you about or to recommend possible treatment options or alternatives that may be of interest to you, or to provide appointment reminders.

**For Distribution of Health-Related Benefits and Services.** The Plan may use or disclose your health information to provide to you information regarding health-related benefits and services that may be of interest to you.

**To Business Associates.** The Plan may disclose your health information to third parties that is hires to provide administrative services with respect to your benefits under the Plan. These third parties are referred to as Business Associates and they must agree in writing to protect the privacy, security and confidentiality of your health information. Examples of Business

Associates are the attorneys who perform legal services on behalf of the Plan and the consultants who provide utilization reviews and cost analysis with respect to specific benefits provided by the Plan.

**For Disclosure to the Plan Sponsor.** The Board of Trustees of the Cleveland Bakers and Teamsters Health and Welfare Fund is the Plan Sponsor for the Plan. The Plan may disclose your health information to the Plan Sponsor for the plan administration functions performed by the Plan Sponsor on behalf of the Plan. In addition, the Plan may provide summary health information to the Plan Sponsor so that the Plan Sponsor may solicit premium bids from health insurers or modify, amend or terminate the plan. The Plan also may disclose information to the Plan Sponsor regarding whether you or your eligible dependents are participating in the health plan.

**To Contributing Employer:** The Plan may disclose to your Contributing Employer whether you are enrolled in, or disenrolled in, the Plan.

**Other Disclosures:** Other Disclosures that the Plan may make:

- To your personal representative appointed by you or as designated by law.
- To a family member, friend or other person, for the purpose of helping you with our health care or health care payment if you are in an emergency situation and you cannot give your agreement to the plan to do so.

**When Legally Required.** The Plan will disclose your health information when it is required to do so by any federal, state or local law. For example, we may disclose your health information when by a court order in a litigation proceeding such as a malpractice action.

**To Conduct Health Oversight Activities.** The Plan may disclose your health information to a health oversight agency for authorized activities including audits, inspections, licensure, civil administrative or criminal investigations, or disciplinary action. The Plan, however, may not disclose your health information if you are the subject of an investigation and the investigation does not arise out of or is not directly related to your receipt of health care or public benefits.

**In Connection With Judicial and Administrative Proceedings.** As permitted or required by state law, the Plan may disclose your health information in the course of any judicial or administrative proceeding in response to an order of a court or administrative tribunal as expressly authorized by such order or in response to a subpoena, discovery request or other lawful process, but only when the Plan makes reasonable efforts to either notify you about the request or to obtain in order protecting your health information.

**For Law Enforcement Purposes.** As permitted or required by state law, the Plan may disclose your health information to a law enforcement official for certain law enforcement purposes, including, but not limited to, if the Plan has a suspicion that your death was a result of criminal conduct or in an emergency to report potential criminal activity.

**In the Event of a Serious Threat to Health or Safety.** The Plan may, consistent with applicable law and ethical standards of conduct, disclose your health information if the Plan, in

good faith, believes that such disclosure is necessary to prevent or lessen a serious and imminent threat to your health or safety or to the health and safety of the general public. For example, we may disclose your medical information in a proceeding concerning the licensure of a physician.

**For Specified Government Functions.** In certain circumstances, federal regulations require the Plan to use or disclose your health information to facilitate specified government functions related to the military and veterans, national security and intelligence activities, protective services for the president and others, and correctional institutions and inmates.

**For Workers' Compensation.** The Plan may release your health information to the extent necessary to comply with laws related to worker's compensation or similar programs. These programs provide benefits for injuries or illnesses that are work-related.

### **AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION**

Other than as stated above, the Plan will not disclose your health information other than with your written authorization. If you authorize the Plan to use or disclose your health information, you may revoke that authorization in writing at any time.

### **YOUR RIGHTS WITH RESPECT TO YOUR HEALTH INFORMATION**

You have the following rights regarding your health information that the Plan maintains:

**Right to Request Restrictions.** You have the right to request restrictions on certain uses and disclosure of your health information. You have the right to request a limit in the Plan's disclosure of your health information to someone involved in the payment of your care. However, the Plan is not required to agree to your request for restrictions. If you wish to make a request for restrictions, please contact the Privacy Official, Laura A. Karcher (9665 Rockside Road, Suite C, Valley View, OH, 44125-6233; Phone: 216-781-6858; Fax: 216-524-7920).

**Right to Receive Confidential Communications.** You have the right to request that the Plan communicate with you in a particular way if you believe that the disclosure of your health information could endanger you. For example, you may ask that the Plan only communicate with you at a certain telephone number or by e-mail. If you wish to receive confidential communications, please make your request in writing to the Privacy Official, Laura A. Karcher (9665 Rockside Road, Suite C, Valley View, OH 44125-6233; Phone: 216-781-6858 Ext. 199; Fax: 216-524-7920). The request will take a period of time to process from the date that it is received. You will receive a letter confirming the activation of the alternate address. All communications regarding your health information will be sent to this alternate address once this request has been received, processed and approved or until you notify the Plan otherwise. Use of an alternate address cannot be applied to communications sent prior to the processing of your request. The Plan will attempt to honor your reasonable requests for confidential communications.

**Right to Inspect and Copy Your Health Information.** You have the right to inspect and copy your health information. A request to inspect and copy records containing your health information must be made in writing to the Privacy Official, Laura A. Karcher (9665 Rockside Road, Suite C, Valley View, OH 44125-6233; Phone: 216-781-6858; Fax: 216-524-7920). If you

request a copy of your health information, the Plan may charge a reasonable fee for copying, mailing, or other costs associated with your request, as applicable.

**Right to Amend Your Health Information.** If you believe that your health information records are inaccurate or incomplete, you may request that the Plan amend the records. Such a request may be made as long as the information is maintained by the Plan. A request for an amendment of records must be made in writing to the Privacy Official, Laura A. Karcher (9665 Rockside Road, Suite C, Valley View, OH 44125-6233; Phone: 216-781-6858; Fax: 216-524-7920), and include the health information that you are requesting be amended as well as an explanation as to why you believe the health information is incorrect or incomplete. The plan may deny the request if it does not include a reason to support the amendment. The request also may be denied if your health information records were not created by the Plan, if the health information you are requesting to amend is not part of the Plan's records, if the health information you wish to amend falls within an exception to the health information you are permitted to inspect and copy, or if the Plan determines the records containing your health information are accurate and complete. The Plan cannot amend health information that it did not create and will refer you to the provider of health care service if you are requesting an amendment to diagnosis or treatment information. You have the right to an appeal if your request for an amendment is denied.

**Right to an Accounting of Disclosures.** You have the right to request a list of certain disclosures of your health information of which the Plan is required to keep a record under the Privacy Rule, such as disclosures for purposes outside of treatment, payment or health care operations. The request must be made in writing to the Privacy Official, Laura A. Karcher (9665 Rockside Road, Suite C, Valley View, OH 44125-6233; Phone: 216-781-6858; Fax: 216-524-7920), and include a statement explaining your specific request. The request should specify the time period for which you are requesting the information, but may not start earlier than April 14, 2003. Accounting requests may not be made for periods of time going back more than six (6) years. The Plan will provide the first accounting you request during any 12-month period without charge. Subsequent accounting requests may be subject to a reasonable cost-based fee. The Plan will inform you in advance of the fee, if applicable.

**Right to a Paper Copy of this Notice.** You have a right to receive a paper copy of this Notice at any time, even if you have received this Notice previously or agreed to receive the Notice electronically. To obtain a paper copy, please contact the Privacy Official, Laura A. Karcher (9665 Rockside Road, Suite C, Valley View, OH 44125-6233; Phone: 216-781-6858 Ext. 199; Fax: 216-524-7920).

### **DUTIES OF THE PLAN**

The Plan is required by law to maintain the privacy of your health information as set forth in this Notice and to provide to you this Notice of its duties and privacy practices. The Plan is required to abide by the terms of this Notice, which may be amended from time to time. The Plan reserves the right to change the terms of this Notice and to make the new Notice provisions effective for all health information that it maintains. If the Plan changes its policies and procedures, the Plan will revise the Notice and will provide a copy of the revised Notice to you within 60 days of the change. You have the right to file a complaint with the Plan and to the Secretary of the Department of Health and Human Services if you believe that your privacy rights have been violated. Any complaints to the Plan should be made in writing to the Privacy Official, Laura A. Karcher. The Plan encourages you to express any concerns you may have regarding the privacy of your information. You will not be retaliated against in any way for filing a complaint.

**CONTACT PERSON**

The Plan has designated the Privacy Contact (Barbara M. Smith) and the Privacy Official (Laura A. Karcher) as its contact people for all issues regarding patient privacy and your privacy rights. You may contact the Privacy Contact and the Privacy Official at 9665 Rockside Road, Suite C, Valley View, OH 44125-6233 (Phone: 216-781-6858; Fax: 216-524-7920).

**IF YOU HAVE ANY QUESTIONS REGARDING THIS NOTICE, PLEASE CONTACT BARBARA M. SMITH (PRIVACY CONTACT) OR LAURA A. KARCHER (PRIVACY OFFICIAL) AT:**

Cleveland Bakers and Teamsters Health and Welfare Fund  
9665 Rockside Road, Suite C  
Valley View, OH 44125-6233  
Phone: 216-781-6858  
Fax: 216-524-7920

## **EXHIBIT 5**

## ***NOTICE OF PRIVACY POLICY***

**THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.**

IBEW-NECA BENEFITS ADMINISTRATION ASSOCIATION is aware of how important your privacy is to you, therefore, we have created this privacy statement in order to demonstrate our firm commitment to privacy.

This notice will tell you about the ways in which we may use and disclose medical information about you. We also describe your rights and certain obligations we have regarding the use and disclosure of medical information.

We are required by law to:

- Make sure that medical information that identifies you is kept private by implementing reasonable and appropriate physical, administrative, and technical safeguards to protect the information;
- Give you this notice of our legal duties and privacy practices with respect to medical information about you; and
- Follow the terms of the notice that is current and in effect.
- Train our personnel concerning privacy and confidentiality.
- Implement a sanction policy to discipline those who breach privacy/confidentiality or our policies with regard thereto.

### **EXAMPLES OF HOW WE MAY USE AND DISCLOSE MEDICAL INFORMATION ABOUT YOU FOR TREATMENT, PAYMENT AND HEALTH OPERATIONS.**

- **As Required By Law.** We will disclose medical information about you when required to do so by federal, state or local law.
- **Business Associates.** We provide some services through contracts with business associates. An example is if we require the services of legal counsel. When we use these services, we may disclose your health information to the business associates so that they can perform the function(s) that we have contracted with them to do. To protect your private health information, we require the business associates sign an agreement requiring them to appropriately safeguard your information.

- **For Payment.** We may use and disclose medical information about you so that the treatment and services you received at a health care facility may be paid to the facility or to reimburse you. We may also give prior approval to the health care facility or to determine whether our plan will cover the treatment.
- **Individuals Involved in Your Care or Payment for Your Care.** We may release medical information about you to a friend or family member who is involved in your medical care. We may also give information to someone who helps pay for your care.
- **Workers' Compensation.** We may release information about you for workers' compensation or similar programs. These programs provide benefits for work-related injuries or illness.
- **Federal Department of Health and Human Services (DHHS).** Under the privacy standards, we must disclose your protected health information to DHHS as necessary to determine our compliance with those standards.
- **Lawsuits and Disputes.** If you are involved in a lawsuit or a dispute, we may disclose medical information about you in response to a court or administrative order. We may also disclose medical information about you in response to a subpoena, discovery request, or other lawful process by someone else involved in the dispute, but only if efforts have been made to tell you about the request or to obtain an order protecting the information requested.
- **Inmates.** If you are an inmate of a correctional institution or under the custody of a law enforcement official, we may release medical information about you to the correctional institution or law enforcement official. This release would be necessary (1) for the institution to provide you with health care; (2) to protect your health and safety or the health and safety of others; or (3) for the safety and security of the correctional institution.

## **YOUR RIGHTS REGARDING MEDICAL INFORMATION ABOUT YOU**

You have the following rights regarding medical information we maintain about you:

- **Right to Inspect and Copy.** You have the right to inspect and copy medical information that may have been used to make decisions about your care. Usually, this includes medical and billing records, but does not include psychotherapy notes.

To inspect and copy medical information about you, you must submit your request in writing to: HIPAA Privacy/Security Compliance Officer, NECA-IBEW Welfare Trust Fund, 2120 Hubbard Avenue, Decatur, IL 62526-2871. If you request a copy of the information, we may charge a fee for the costs of copying, mailing or other supplies associated with your request.

We may deny your request to inspect and copy in certain very limited circumstances. If you are denied access to medical information, you may request that the denial be reviewed. Another individual chosen by NECA-IBEW Welfare Trust Fund will review your request and the denial. The person conducting the review will not be the person who denied your request. We will comply with the outcome of the review.

- **Right to Amend.** If you feel that medical information we have about you is incorrect or incomplete, you may ask us to amend the information. You have the right to request an amendment for as long as the information is kept by or for NECA-IBEW Welfare Trust Fund.

To request an amendment, your request must be made in writing and submitted to: HIPAA Privacy/Security Compliance Officer, NECA-IBEW Welfare Trust Fund, 2120 Hubbard Avenue, Decatur, IL 62526-2871. In addition, you must provide a reason that supports your request.

We may deny your request for an amendment if it is not in writing or does not include a reason to support the request. In addition, we may deny your request if you ask us to amend information that:

- Was not created by us, unless the person or entity that created the information is no longer available to make the amendment;
  - Is not part of the medical information kept by or for the NECA-IBEW Welfare Trust Fund;
  - Is not part of the information which you would be permitted to inspect and copy; or
  - Is accurate and complete.
- **Right to an Accounting of Disclosures.** You have the right to request an “accounting of disclosures.” This is an accounting of uses and disclosures other than for treatment, payment, and health care operations.

To request this list or accounting of disclosures, you must submit your request in writing to: HIPAA Privacy/Security Compliance Officer, 2120 Hubbard Avenue, Decatur, IL 62526-2871. Your request must state a time period, which may not be longer than six (6) years and may not include dates before April 14, 2003. Your request should indicate in what form you want this list (for example, on paper, electronically). The first list you request within a 12-month period will be free. For additional lists, we may charge you for the costs of providing the list. We will notify you of the cost involved and you may choose to withdraw or modify your request at that time before costs are incurred.

- **Right to Request Restrictions.** You have the right to request a restriction or limitation on the medical information we use or disclose about you for treatment, payment or health care operations. You also have the right to request a limit on the medical information we disclose about you to someone who is involved in your care or the payment for your care, like a family member or friend. For example, you could ask that we not use or disclose information about a surgery.

The right to request restriction does not extend to uses or disclosures permitted or required under the following sections of the federal privacy regulations: § 164.502(a)(2)(i) (disclosures to you), 164.510(a) (for facility directories, but note that you have the right to object to such uses), or 164.512 (uses and disclosures not requiring a consent or an authorization). The latter uses and disclosures include, for example, those required by law, such as mandatory communicable disease reporting. In those cases, you do not have a right to request restriction. The consent to use and disclose your individually identifiable health information provides the ability to request restriction. We do not, however, have to agree to the restriction. If we do, we will adhere to it unless you request otherwise or we give you advance notice.

To request restrictions, you must make your request in writing to: HIPAA Privacy/Security Compliance Officer, NECA-IBEW Welfare Trust Fund, 2120 Hubbard Avenue, Decatur, IL 62526-2871. In your request, you must tell us (1) what information you want to limit; (2) whether you want to limit our use, disclosure or both; and (3) to whom you want the limits to apply, for example, disclosures to your spouse.

- **Right to Request Confidential Communications.** You have the right to request that we communicate with you about medical matters in a certain way or at a certain location. For example, you can ask that we only contact you at work or by mail.

To request confidential communications, you must make your request in writing to: HIPAA Privacy/Security Compliance Officer, NECA-IBEW Welfare Trust Fund, 2120 Hubbard Avenue, Decatur, IL 62526-2871. We will not ask you the reason for your request. We will accommodate all reasonable requests. Your request must specify how or where you wish to be contacted.

- **Right to a Paper Copy of This Notice.** You have the right to a paper copy of this notice. You may ask us to give you a copy of this notice at any time. Even if you have agreed to receive this notice electronically, you are still entitled to a paper copy of this notice.

You may obtain a copy of this notice at our website, [www.neca-ibew.org](http://www.neca-ibew.org). To obtain a paper copy of this notice, notify: HIPAA Privacy/Security Compliance Officer, NECA-IBEW Welfare Trust Fund, 2120 Hubbard Avenue, Decatur, IL 62526-2871.

### CHANGES TO THIS NOTICE

We reserve the right to change this notice. We reserve the right to make the revised or changed notice effective for protected health information we already have about you as well as any information we receive in the future. Any revised notice and the effective date of such notice will be mailed to the last known address that you have given us.

### COMPLAINTS

If you believe your privacy rights have been violated, you may file a complaint with the NECA-IBEW Welfare Trust Fund Office or with the Secretary of the Department of Health and Human Services. If you have questions and/or would like additional information, contact the HIPAA Privacy/Security Compliance Officer, at 1-800-765-4239, extension 161. All complaints must be submitted in writing and mailed to: .  
HIPAA Privacy/Security Compliance Officer, NECA-IBEW Welfare Trust Fund, 2120 Hubbard Avenue, Decatur, IL 62526-2871.

**You will not be penalized for filing a complaint.**

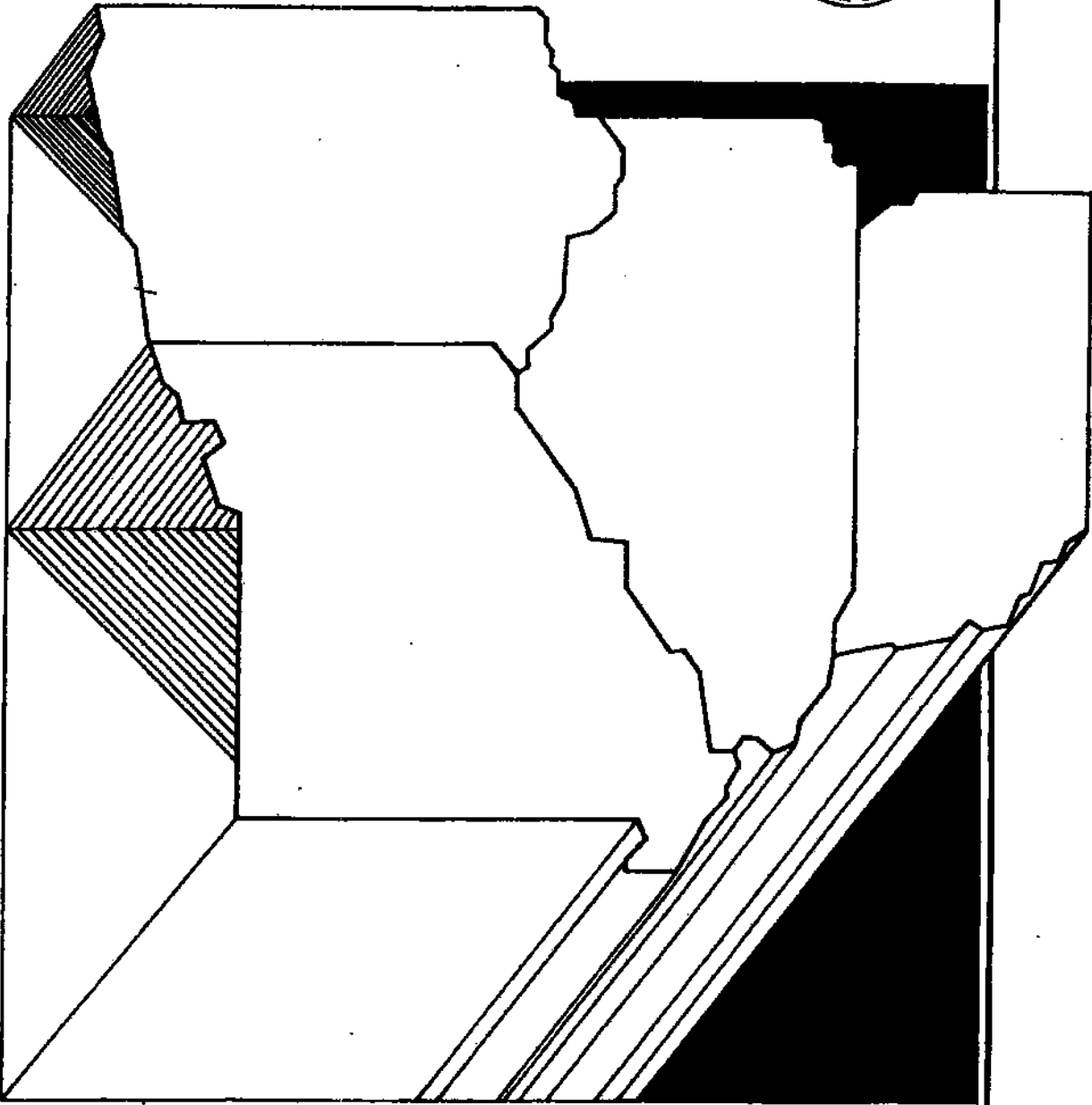
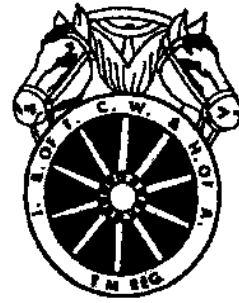
### OTHER USES OF PROTECTED HEALTH INFORMATION

Other uses and disclosures of protected health information not covered by this notice or the laws that apply to us will be made only with your written authorization. If you provide us authorization to use or disclose protected health information about you, you may revoke that permission, in writing, at any time. If you revoke your authorization, we will no longer use or disclose protected information about you for the reasons covered by your written authorization. You understand that we are unable to take back any disclosures we have already made with your authorization.

## **EXHIBIT 6**

# MIDWESTERN TEAMSTERS

Health and Welfare Fund



JANUARY 2005

MWT00001

## **USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (PHI)**

### **How the Plan Uses And Discloses Your Protected Health Information**

The Plan will use your protected health information (PHI) to the extent and in accordance with the uses and disclosures permitted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Specifically, the Plan will use and disclose protected health information for purposes related to health care treatment, payment for health care, and health care operations.

The Plan will use and disclose your PHI as required by law and as permitted by your authorization or the authorization of your beneficiary. With an authorization, the Plan will disclose PHI to a Retirement Fund, disability plan, reciprocal benefit plans and workers' compensation insurers for purposes related to administration of these plans.

### **Definition Of Payment**

Payment includes activities by the Plan to obtain premiums or determine or fulfill its responsibility for coverage and provision of Plan benefits that relate to an individual to whom health care is provided. These activities include, but are not limited to, the following:

1. Determination of eligibility, coverage, and cost sharing amounts (e.g cost of a benefit, Plan maximums, and copayments as determined for an individual's claim);
2. Coordination of benefits;
3. Adjudication of health benefit claims (including appeals and other payment disputes);
4. Subrogation of health benefit claims;
5. Establishing employee contributions;
6. Risk adjusting amounts due based on enrollee health status and demographic characteristics;
7. Billing, collection activities and related health care data processing;
8. Claims management and related health care data processing, including auditing payments, investigating and resolving payment disputes and responding to participant (and their representatives) inquiries about payments;
9. Obtaining payment under a contract for reinsurance (including stop-loss and excess of loss insurance);
10. Medical necessity reviews, or reviews of appropriateness of care or justification of charges;
11. Utilization review, including precertification, preauthorization, concurrent review and retrospective review;
12. Disclosure to consumer reporting agencies related to collection of premiums or reimbursement (the following PHI may be disclosed for payment purposes: name and address, date of birth, SSN, payment history, account number, and name and address of the provider and/or health plan); and
13. Reimbursement to the Plan

### **Definition Of Health Care Operations**

Health Care Operations include, but are not limited to, the following activities:

1. Quality Assessment;
2. Population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, disease management, contracting of health care providers and patients with information about treatment alternatives; and related functions;
3. Rating provider and Plan performance, including accreditation, certification, licensing, or credentialing activities;
4. Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or

- placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance);
- 5. Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;
- 6. Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies;
- 7. Business management and general administrative activities of the entity, including, but not limited to:
  - A. Management activities relating to implementation of and compliance with the requirements of HIPAA Administrative Simplification;
  - B. Customer service, including provision of data analyses for policyholders, Plan sponsors, or other customers;
  - C. Resolution of internal grievances; and
  - D. Due diligence in connection with the sale or transfer of assets to a potential successor in interest, if the potential successor in interest is a covered entity or, following completion of the sale or transfer, will become a covered entity.

#### **The Plan's Disclosure Of Protected Health Information To The Board Of Trustees**

For purposes of this section the Board of Trustees is the Plan Sponsor. The Plan will disclose PHI to the Plan Sponsor only upon receipt of a certification from the Plan Sponsor that the Plan Documents have been amended to incorporate the following provisions:

With respect to PHI, the Plan Sponsor agrees to:

1. Not use or further disclose the information other than as permitted or required by this Summary Plan Description or as required by law;
2. Ensure that any agents, including a subcontractor, to whom the Plan Sponsor provides PHI received from the Plan agree to the same restrictions and conditions that apply to the Plan Sponsor with respect to such information;
3. Not use or disclose the information for employment-related actions and decisions unless authorized by the individual;
4. Not use or disclose information in connection with any other benefit or employee benefit Plan of the Plan Sponsor unless authorized by the individual;
5. Report to the Plan any use or disclosure of the information of which it becomes aware that is inconsistent with the uses or disclosures provided for in this document;
6. Make PHI available to the individual in accordance with the access requirements of HIPAA;
7. Make PHI available for amendment and incorporate any amendments to PHI in accordance with HIPAA;
8. Make the information available that is required to provide an accounting of disclosures;
9. Make internal practices, books, and records in relating to the use and disclosure of PHI received from the group health Plan available to the Secretary of HHS for purposes of determining compliance by the group health Plan with HIPAA;
10. If feasible, return or destroy all PHI received from the Plan that the Plan Sponsor still maintains in any form and retain no copies of such information when no longer needed for the purpose for which disclosure was made. If return or destruction is not feasible, limit further uses and disclosures to those purposes that make the return or destruction infeasible.

Adequate separation between the Plan and the Plan Sponsor will be maintained. Therefore, in accordance with HIPAA, only the following employees or classes of employees will be given access to PHI.

1. The Plan Administrator; and
2. Staff designated by the Plan Administrator.

The persons described above will only have access to and will only use and disclose PHI for Plan administration functions that the Plan sponsor performs for the plan. If these persons do not comply with this Summary Plan Description, the Plan Sponsor will provide a mechanism for resolving issues of noncompliance, including disciplinary sanctions.

## **EXHIBIT 7**

**SOUTHERN ILLINOIS LABORERS' & EMPLOYERS  
HEALTH & WELFARE FUND**

**2035 Washington Avenue  
Cairo, Illinois 62914  
618 -734 -0773 or 800-327-4532**

**www.silehw.org**

**UNION TRUSTEES**

**Edward M. Smith - Vice President & Regional Manager  
Laborers' International Union of North America  
Midwest Region Office  
1 North Old State Capital Plaza Suite 525  
Springfield, IL 62701  
(217) 522- 3381**

**Charles Aly -Business Manager  
Laborers' Local 773  
P.O. Box 1770  
Marion, IL 62959  
(618) 993-5773**

**Bob Bandy -Field Representative  
Southern & Central Illinois Laborers' District Council  
805 West DeYoung St. Ste D  
P.O. Box 1240  
Marion, IL 62959  
(618) 998-1787**

**Rick Schewe -Business Manager  
Laborers' Local 459  
100 N. 17<sup>th</sup> St  
Belleville, IL 62226  
(618) 233-4121**

**Flint Taylor - Business Manager  
Laborers' Local 1197  
P.O. Box 56  
McLeansboro, IL 62859  
(618) 643-2757**

**John R. Taylor -Business Manager/Secretary-Treasurer  
Southern & Central Illinois Laborers' District Council  
805 West DeYoung St. Ste D  
P.O. Box 1240  
Marion, IL 62959  
(618) 998-1787**

**CONSULTANT TO THE TRUSTEES**

**Kenneth A. Thorp, CLU, CEBS**

**EMPLOYER TRUSTEES**

**Tom Arnold, Sr.- President  
Martz & Oren  
P.O. Box 310  
400 W. Jefferson Ave.  
Effingham, IL  
(217) 342-2111**

**Fred Crews -Executive Director/Secretary-Treasurer  
Egyptian Contractors Association  
P. O. Box 879  
Carbondale, IL 62903  
(618) 529-7600**

**Ray Hawkins - Director of Labor Relations  
AGC of Illinois  
3219 Executive Park Dr.  
Springfield, IL 62703  
(217) 789-2650**

**Henry Rohwedder - President  
Hank's Excavating & Landscaping Inc.  
5825 West State Rt 161  
Belleville, IL 62223  
(618)398-5556**

**Steve Starwalt -Vice President  
Wortman-Starwalt  
1303 W. McGrath  
P.O. Box 1306  
Effingham, IL 62401  
(217) 347-0501**

**Tom Tinsley - Secretary/Treasurer  
Wabash Asphalt Company, Inc.  
P.O. Box 307  
Mt. Carmel, IL 62863  
(618) 262-7131**

**FUND ATTORNEY**

**Cavanagh & O'Hara**

## **ARTICLE 15 - PRIVACY AMENDMENT**

### **SECTION 1**

#### **DEFINITIONS**

For purposes of the Privacy Amendment, the following definitions shall apply. Terms used, but not otherwise defined, in this Privacy Amendment shall have the same meaning as those terms in 45 CFR §160.103 and 45 CFR §164.501.

**CFR** - Code of Federal Regulations.

**Disclosure** - The release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.

**Individually Identifiable Health Information** - Information that:

1. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
2. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
3. That identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

**Privacy Rule** - The Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

**Protected Health Information (PHI)** - Individually identifiable health information that is:

1. Transmitted by electronic media;
2. Maintained in electronic media; or
3. Transmitted or maintained in any other form or medium. This definition does not include education records covered by the Family Educational Right and Privacy Act.

**Required by Law** - A mandate contained in law that compels the Plan to make a use or disclosure of PHI and this is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court or grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

**Secretary** - The Secretary of the Department of Health and Human Services or his/her designee.

**U.S.C.** - United States Code.

**Use** - With respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

### **SECTION 2**

#### **ROLE OF THE PLAN SPONSOR**

The Plan Sponsor performs certain Plan Administration functions on behalf of the Plan and requires access to Protected Health Information (PHI) for the purpose of performing such Plan Administration functions. The Plan will only disclose PHI to Plan Sponsor upon receipt of a Certification of Compliance with the Standards for Privacy of Individually Identifiable Health Information. Plan Sponsor will not use or disclose PHI in any manner that is inconsistent with this Privacy Amendment.

### **SECTION 3**

#### **PERMITTED USES AND DISCLOSURES**

The Plan Sponsor may use your PHI for any of the following purposes:

1. Obtaining premiums
2. Coverage determinations
3. Obtaining or providing reimbursement for health care
4. Eligibility determinations
5. Coordination of Benefits determinations
6. Claim adjudication
7. Subrogation
8. Billing
9. Claims management
10. Filing stop loss claims
11. Medical necessity reviews
12. Utilization review
13. Review for justification of charges
14. Pre-certification
15. Pre authorization
16. Concurrent review
17. Retrospective review
18. Case management and/or coordination
19. Providing treatment alternatives
20. Credentialing
21. Licensing
22. Certification
23. Accreditation
24. Training
25. Evaluating health plan performance
26. Underwriting
27. Premium rating
28. Ceding, securing or placing stop loss contracts
29. Other activities related to renewal or replacement of health insurance contracts
30. Medical review
31. Legal services
32. Auditing
33. Fraud abuse and detection
34. Compliance
35. Cost-management and planning analyses
36. Administration
37. Quality Assessment
38. Customer service
39. Grievance resolution
40. Due diligence
41. Fund-raising for the covered entity
42. De-identifying PHI
43. As Required by Law

# **EXHIBIT W**

PH

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

SOUTHERN ILLINOIS LABORERS' AND EM- )  
PLOYERS HEALTH AND WELFARE FUND, )  
NECA-IBEW WELFARE TRUST FUND, and )  
MIDWESTERN TEAMSTERS HEALTH AND )  
WELFARE FUND, )  
individually, and )  
on behalf of all others similarly situated, )  
  
Plaintiffs, )  
  
v. )  
  
PFIZER INC., )  
  
Defendant. )

No. 06CV1818

JUDGE JOHN W. DARRAH

MAGISTRATE JUDGE  
GERALDINE SOAT BROWN

**STIPULATION AND ORDER  
FOR PROTECTION OF CONFIDENTIAL INFORMATION**

WHEREAS pursuant to Federal Rule of Civil Procedure 26(c), the Court and the parties deem it appropriate to limit the disclosure of certain confidential information, as set forth below, and the parties to this action, by counsel, have stipulated and agreed to give effect to the stipulations set forth below.

**IT IS HEREBY ORDERED THAT:**

1. **Discovery Material.** This Order applies to all products of discovery and all information derived therefrom, including, but not limited to, all documents and deposition testimony and any copies, excerpts or summaries thereof, obtained by any party pursuant to the requirements of any court order, requests for production of documents, requests for admissions, interrogatories or subpoena.

2. **Confidential Discovery Material.** Discovery material containing trade secrets, or other confidential information or proprietary research, development, manufacturing or commercial or business information, which the producing party has a reasonable basis for treating as secret or commercially sensitive, may be designated as "Confidential." Without prejudice to the right of a party to object to the production of the following information or of a party to seek production, the information subject to such designation may include the producing party's:

- (a) Names of customers or patients;
- (b) Proprietary licensing, distribution, marketing, advertising, design, development, research and manufacturing information regarding products and medicines, whether previously or currently marketed or under development;
- (c) Clinical studies;
- (d) Information concerning competitors;
- (e) Production information;
- (f) Personnel records and information;
- (g) Financial information not publicly filed with any federal or state regulatory authorities;
- (h) Information submitted to any governmental or regulatory agency, which information is exempt from public disclosure;
- (i) The medical, tax and personal financial records of the Plaintiffs in this litigation or their current or former members and beneficiaries; and
- (j) Information reflecting commercially sensitive marketing strategy, marketing plans or marketing analysis.

The parties agree that information that is publicly available (other than information disclosed in violation of the protective order) shall not be designated as Confidential.

3. (a) The parties agree that confidential discovery material will be used only for the litigation of this action, *Southern Illinois Laborers' and Employers Health and Welfare Fund, NECA-IBEW Welfare Trust Fund, and Midwestern Teamsters Health and Welfare Fund, individually, and On Behalf of All Other Similarly Situated v. Pfizer, Inc.*, ("Litigation"), or any related litigation, including any appeals of this litigation. Confidential discovery material will not be disclosed except in accordance with paragraphs 3(b) and 6.

(b) Prior to being given access to confidential discovery material, any person falling within paragraphs 6(a)(vi) or 6(a)(viii) shall be provided with a copy of this Order and shall execute a copy of the Endorsement of Protective Order, attached as Exhibit A. Counsel providing such access to confidential discovery material shall retain copies of the Endorsement(s) of Protective Order and shall provide them to counsel producing confidential discovery material as provided below. For testifying experts, a copy of the Endorsement of Protective Order executed by the testifying experts shall be furnished to counsel for the party who produced the confidential discovery material to which the expert has access, either at the time the confidential discovery material is provided to the testifying expert, or at the time the expert's designation is served, whichever is later.

4. Confidential discovery material, if a writing, shall have the following language stamped on the face of the writing, or shall otherwise have such language clearly marked:

**Confidential**  
**Subject to Protective Order**

Such stamping or marking will take place prior to production by the producing person, or subsequent to selection by the receiving party for copying but prior to the actual copying if done expeditiously. The stamp shall be affixed in such manner as not to obliterate or obscure any written matter. In the case of deposition testimony, confidentiality designations shall be made within 14 days after the transcript has been received by counsel making the designation, and shall specify the testimony being designated confidential by page and line number(s). Until the expiration of the 14-day period, the entire text of the deposition, including exhibits, shall be treated as confidential under this Order. In the event that the producing person or party inadvertently fails to designate discovery material as confidential in this or any other litigation, it may make such a designation subsequently by notifying all parties to whom such discovery material was produced, in writing as soon as practicable. After receipt of such notification, the parties to whom production has been made shall treat the designated discovery material as confidential, subject to their right to dispute such designation in accordance with paragraph 7.

5. Confidential discovery material shall be used solely for the purposes of this litigation and for no other purpose without written approval from the Court or the prior written consent of the producing person or party. All persons receiving or given access to confidential discovery material in accordance with the terms of this Order consent to the continuing jurisdiction of the Court for the purposes of enforcing this Order and remedying any violations thereof.

6. (a) Confidential discovery material shall not be disclosed to anyone other than the following categories of persons:

(i) The Court (and any appellate court), including court personnel, jurors, and alternate jurors only in the manner provided in paragraph 9 below.

(ii) If produced by Plaintiffs, Defendant's in-house counsel, paralegals and clerical support staff, and outside counsel, including any attorneys employed by or retained by Defendant's outside counsel who are assisting in connection within this litigation, and the paralegal, clerical, secretarial and other staff employed or retained by such outside counsel or retained by the attorneys employed by or retained by Defendant's outside counsel.

(iii) If produced by any Defendant, the named Plaintiffs to this litigation, Plaintiffs' attorneys in this litigation, including any paralegal, clerical, secretarial, and other staff employed or retained by such counsel.

(iv) If produced by any Defendant, outside counsel for any other Defendants, including any attorneys employed by or retained by any other Defendant's outside counsel who are assisting in connection with this litigation, and the paralegal, clerical, secretarial and other staff employed or retained by outside counsel.

(v) Court reporters (including persons operating video recording equipment at depositions) and persons preparing transcripts of testimony to the extent necessary to prepare such transcripts.

(vi) Retained experts, advisors and consultants, including persons directly employed by such experts, advisors and consultants (collectively "Experts"), but only to the extent necessary to perform their work in connection with this litigation.

(vii) The persons who authored the confidential discovery material or who received such confidential discovery material in the ordinary course of business.

(viii) Such persons as the undersigned shall consent to in writing before the proposed disclosure.

(b) All parties and their respective counsel, paralegals and the employees and assistants of all counsel receiving discovery material shall take all steps reasonably necessary to prevent the disclosure of confidential discovery material other than in accordance with the terms of this Order.

(c) Disclosure of confidential discovery material other than in accordance with the terms of this Order may subject the disclosing person to such sanctions and remedies as the Court may deem appropriate, including without limitation, contempt, injunctive relief and damages.

7. (a) If at any time a party wishes for any reason to dispute a designation of discovery material as confidential hereunder, such party shall notify the designating party of such dispute in writing, specifying the discovery material in dispute by exact document numbers and the precise nature of the dispute with regard to each such document or other discovery material; if the parties are unable to resolve the dispute amicably, any party may apply by motion to the Court for a ruling as to whether the designated discovery material may, in accordance with this Order, properly be treated as confidential, provided such motion is made within 30 days from the date on which the parties, after good faith attempt, could not resolve the dispute or such other time period as the parties may agree. The designating party shall have the burden of proof on such motion to establish the propriety of its confidentiality designation.

(b) All discovery material designated as confidential under this Order, whether or not such designation is in dispute pursuant to subparagraph 7(a) above, shall retain that designation and be treated as confidential in accordance with the terms hereof unless and until:

(i) the time period for filing a Motion for Protective Order set in paragraph 7(a) has expired without the filing of any such Motion.

(ii) the producing party agrees in writing that the material is no longer confidential and subject to the terms of this Order; or

(iii) ten days after the expiration of the appeal period of an Order of this Court that the matter shall not be entitled to confidential status (or such longer time as ordered by this Court if the Order on appeal is not subject to a stay).

(c) The parties shall negotiate in good faith before filing any motion relating to this Order.

8. Any non-party who is producing discovery material in this litigation may subscribe to and obtain the benefits of the terms and protections of this Order by designating as "Confidential" the discovery materials that the non-party is producing as set forth in paragraphs 2 and 4.

9. Any confidential discovery material that is filed with the Court, and any pleading, motion or other paper filed with the Court containing or disclosing any such confidential discovery shall be filed under seal and shall bear the legend:

**THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION COVERED BY A PROTECTIVE ORDER OF THE COURT AND IS SUBMITTED UNDER SEAL PURSUANT TO THAT PROTECTIVE ORDER. THE CONFIDENTIAL CONTENTS OF THIS DOCUMENT MAY NOT BE DISCLOSED WITHOUT EXPRESS ORDER OF THE COURT.**

Said confidential discovery material and/or other papers shall be kept under seal until further order of the Court; however, said confidential discovery material and other papers filed under

seal shall be available to the Court and counsel of record, and to all other persons entitled to receive the confidential information contained therein under the terms of this Order.

10. (a) Except as provided herein, nothing in this Order shall prevent or restrict counsel for any party in any way from inspecting, reviewing, using or disclosing any discovery material produced or provided by that party, including discovery material designated as confidential.

(b) Nothing shall prevent disclosure beyond that permitted under this Order if the producing party consents in writing to such disclosure, or if the Court, after notice to all affected parties, orders such disclosure and that Order is not subject to an appellate stay within 20 days after it is issued.

(c) No disclosure pursuant to this paragraph 10 shall waive any rights or privileges of any party granted by this Order.

11. This Order shall not enlarge or affect the proper scope of discovery in this or any other litigation, nor shall this Order imply that confidential discovery material is properly discoverable, relevant or admissible in this or any other litigation. Each party reserves the right to object to any disclosure of information or production of any documents that the producing party designates as confidential discovery material on any other ground it may deem appropriate.

12. The entry of this Order shall be without prejudice to the rights of the parties, or any one of them, or of any non-party to assert or apply for additional or different protection.

13. All parties and counsel for such parties in this litigation shall make a good faith effort to ensure that their experts, employees and agents comply with this Order. In the event of a change in counsel, retiring counsel shall fully instruct new counsel of their responsibilities under this Order.

14. The terms of this Order shall survive and remain in effect after the termination of this litigation. The parties shall take such measures as are necessary and appropriate to prevent the public disclosure of confidential discovery material, through inadvertence or otherwise, after the conclusion of this litigation.

15. Within 30 days of the termination of this litigation (including any appeals) or such other time as the producing party may agree in writing, the parties shall return the confidential discovery material to counsel for the producing party and/or certify to counsel for the producing party that they destroyed confidential discovery material.

16. If a receiving party or its counsel or expert is served with a subpoena or other process by any court, administrative or legislative body, or any other person or organization which calls for production of any confidential discovery material produced by another party, the party to whom the subpoena or other process is directed shall not, to the extent permitted by applicable law, provide or otherwise disclose such documents or information until 10 business days after notifying counsel for the producing party in writing of all of the following: (1) the information and documentation which is requested for production in the subpoena; (2) the date on which compliance with the subpoena is requested; (3) the location at which compliance with the subpoena is requested; (4) the identity of the party serving the subpoena; and (5) the case name, jurisdiction and index, docket, complaint, charge, civil action or other identification number or other designation identifying the litigation, administrative proceeding or other proceeding in which the subpoena has been issued. The party, counsel or expert receiving the subpoena or other process shall cooperate with the producing party in any proceeding relating thereto.

17. Inadvertent production of documents subject to work-product immunity, the attorney-client privilege or other legal privilege protecting information from discovery shall not constitute a waiver of the immunity or privilege, provided that the producing party shall promptly notify the receiving party in writing of such inadvertent production. If reasonably prompt notification is made, such inadvertently produced documents and all copies thereof, as well as all notes or other work product reflecting the contents of such materials, shall be returned to the producing party or destroyed, upon request, and such returned or destroyed material shall be deleted from any litigation-support or other database. No use shall be made of such documents during depositions or at trial, nor shall they be disclosed to anyone who was not given access to them prior to the request to return or destroy them. The party returning such material then may move the Court for an Order compelling production of the material, but such motion shall not assert as a ground for entering such an order the fact or circumstances of the inadvertent production.

18. This Order does not restrict or limit the use of confidential discovery material at any hearing or trial, which is expected to be the subject of a further protective order and/or appropriate court orders. Prior to any hearing or trial at which the use of confidential discovery material is anticipated, the parties shall meet and confer regarding the use of the confidential discovery material. If the parties cannot agree, the parties shall request the Court to rule on such procedures.

19. Nothing in this Order shall limit or circumscribe in any manner any rights the parties may have under common law or pursuant to any statute, regulation or ethical canon.

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

SOUTHERN ILLINOIS LABORERS' AND EM- )  
PLOYERS HEALTH AND WELFARE FUND, )  
NECA-IBEW WELFARE TRUST FUND, and )  
MIDWESTERN TEAMSTERS HEALTH AND )  
WELFARE FUND, )  
individually, and )  
on behalf of all others similarly situated, )

Plaintiffs, )

v. )

PFIZER INC., )

Defendant. )

No. 06CV1818

JUDGE JOHN W. DARRAH

MAGISTRATE JUDGE  
GERALDINE SOAT BROWN

**EXHIBIT A**  
**ENDORSEMENT OF PROTECTIVE ORDER**

I hereby attest to my Understanding that information or documents designated Confidential are provided to me subject to the Protective Order regarding Confidential Information dated \_\_\_\_\_, 2006 (the "Protective Order"), in the above-captioned litigation; that I have been given a copy of and have read the Protective Order, and that I agree to be bound by its terms. I also understand that my execution of this Endorsement of Protective Order, indicating my agreement to be bound by the Protective Order, is a prerequisite to my review of any information or documents designated as confidential pursuant to the Protective Order.

I further agree that I shall not disclose to others, except in accord with the Protective Order, in any form whatsoever, and that such confidential discovery material and the information contained therein may be used only for the purposes authorized by the Protective Order.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such discovery material and information will continue even after this litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Protective Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United States District Court for the Northern District of Illinois, for purposes of any proceedings relating to enforcement of the Protective Order.

I further agree to be bound by and to comply with the terms of the Protective Order as soon as I sign this Agreement, whether or not the Protective Order has yet been entered as an Order of the Court.

Date:

By: \_\_\_\_\_

Subscribed and sworn to before this  
\_\_\_\_ day of \_\_\_\_\_ 200\_\_.

\_\_\_\_\_  
Notary Public

Plaintiffs and Defendants through their respective counsel hereby stipulate that the Court may enter the Order as set forth above.

IT IS SO ORDERED.

Dated: 12/14/06, 2006



HON. JOHN W. DARRAH  
UNITED STATES DISTRICT JUDGE

AGREED AND CONSENTED TO BY:



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Sidney S. Liebesman  
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ATTORNEYS FOR DEFENDANT PFIZER  
INC

Dated: 12/14, 2006

# **EXHIBIT X**

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

SOUTHERN ILLINOIS LABORERS' AND	)	
EMPLOYERS HEALTH AND WELFARE	)	
FUND; NECA-IBEW WELFARE TRUST	)	
FUND; MIDWESTERN TEAMSTERS	)	
HEALTH AND WELFARE FUND; THE	)	
WELFARE FUND OF TEAMSTERS	)	
LOCAL UNION 863; PLUMBERS AND	)	CIVIL ACTION No. 06-CV-1818
PIPEFITTERS LOCAL UNION 630	)	
WELFARE TRUST FUND; CLEVELAND	)	JUDGE JOHN W. DARRAH
BAKERS AND TEAMSTERS HEALTH	)	
AND WELFARE FUND; ELECTRICAL	)	MAGISTRATE JUDGE
WORKERS BENEFIT TRUST FUND; FIRE	)	GERALDINE SOAT BROWN
& POLICE RETIREE HEALTH CARE	)	
FUND, SAN ANTONIO; LABORERS'	)	
DISTRICT COUNCIL BUILDING AND	)	
CONSTRUCTION HEALTH AND	)	
WELFARE FUND; LABORERS'	)	
DISTRICT COUNCIL HEAVY AND	)	
HIGHWAY UTILITY HEALTH AND	)	
WELFARE FUND; and NEW YORK CITY	)	
POLICE SERGEANTS BENEVOLENT	)	
ASSOCIATION HEALTH & WELFARE	)	
FUNDS, individually, and on behalf of all	)	
others similarly situated,	)	
Plaintiffs,	)	
v.	)	
PFIZER INC.,	)	
Defendant.	)	

**PLAINTIFFS' OBJECTIONS TO MAGISTRATE JUDGE BROWN'S ORDER  
DATED DECEMBER 21, 2007 GRANTING PFIZER'S MOTION TO COMPEL**

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*Lead Counsel for Plaintiffs and Proposed Lead  
Counsel for the Class*

Pursuant to Fed. R. Civ. P. 72(a), Plaintiffs file this Objection to Magistrate Judge Brown's Memorandum Opinion and Order dated December 21, 2007 (the "Order"), granting Defendant Pfizer Inc's ("Pfizer" or the "Company") motion to compel [Dkt 133], to the extent the Order compels the production of documents that are not in Plaintiffs' possession, custody or control and to the extent the Order compels disclosure of participant specific information.<sup>1</sup>

### INTRODUCTION

Plaintiffs' response to Pfizer's document requests is not complicated – where Plaintiffs possessed or controlled documents responsive to Pfizer's document requests, Plaintiffs produced them. If documents have not been produced, they either are not in Plaintiffs' possession or control or do not exist. Moreover, given the operative complaint's theories of liability and damages, disclosure of participant-specific information is unnecessary and harassing.

On December 21, 2007, Magistrate Judge Brown issued the Order granting Pfizer's Motion to Compel. The Order required Plaintiffs to: (i) identify the person(s) who provided, and the circumstances under which Plaintiffs received, certain documents identified as PLCONS000001-002269; (ii) produce responsive documents to the more than seventy categories of documents identified in Pfizer's Motion to Compel; and (iii) produce unredacted versions of documents already produced to Pfizer disclosing participant names and dates of birth. Plaintiffs do not object to complying with the aspect of the Order requiring Plaintiffs to provide certain information regarding the documents identified as PLCONS000001-002269. However, the Order is legally incorrect in compelling the production of unredacted documents disclosing participant names and dates of birth, as well as seventy categories of documents demanded by Pfizer.

First, the Order improperly relieved Pfizer of any burden of proof on its motion to compel, compelling Plaintiffs to produce documents that the Magistrate Judge concluded could be "expected to be in Plaintiffs' possession, custody or control." Order at 9. But the Order's "expectation" ignores the dispositive legal requirement that Pfizer, as the party seeking to compel documents, bore the burden of establishing Plaintiffs' control over such documents. The

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<sup>1</sup> Magistrate Judge Brown's Memorandum Opinion and Order dated December 21, 2007 [Dkt 185], is attached hereto as Exhibit A. On January 4, 2008, Plaintiffs filed a motion and incorporated memorandum of law [Dkt 191] requesting the Court stay Plaintiffs' compliance with the December 21 Order, at a minimum, until ten days after the District Court's final ruling on the Plaintiffs' Objections to the Order. Plaintiffs' motion was granted on January 9, 2008. See [Dkt 194].

Order identifies absolutely no evidence that Pfizer presented establishing control by each of the named Plaintiffs. Pfizer presented none. To dispel any doubt, however, Plaintiffs provide herewith affidavits from each of the individual Plaintiffs affirming that they have produced all responsive documents within their possession, custody or control. To the extent that responsive documents have not been produced, simply put, such documents are not within Plaintiffs' control or do not exist.<sup>2</sup>

Second, in determining that the documents Pfizer demanded are directly relevant to the theory of the Second Amended Complaint ("SAC"), the Order relies, in part, on Magistrate Judge Brown's November 14, 2007 order. *See* Order at 8 (citing Magistrate Judge Brown's November 14, 2007 order at 6). Plaintiffs' Amended Objections to Magistrate Judge Brown's November 14, 2007 Order [Dkt 173] and Plaintiffs' Reply in Further Support of its Amended Objections to Magistrate Judge Brown's November 14, 2007 Order [Dkt 188] explain why Magistrate Judge Brown's application of the relevance principle, given the theory of liability and damages pled in the SAC, is incorrect. The same rationale holds true here. Any documents relating to individual prescriptions of Lipitor (whether on or off label) are of marginal, if any, relevance. Changing the appropriate scope of discovery was the primary purpose behind the filing of the SAC in the first place. Plaintiffs expressly explained this rationale to this Court in seeking leave to file the SAC. Magistrate Judge Brown's decision completely ignores this point.

### **FACTUAL BACKGROUND**

#### **A. Plaintiffs Have Produced All Responsive Documents Within Their Possession, Custody or Control**

To date, Pfizer has served Plaintiffs collectively with more than 1,000 requests for the production of documents. In response to each request, Plaintiffs conducted a search of their records and files to locate responsive documents. Where responsive documents were found, Plaintiffs produced them. Among other things, Plaintiffs' productions include hundreds of pages of Lipitor payment information and documents governing the establishment and operations of the various Funds. In the case where one Plaintiff implemented controls to curb payments for statins – such as Lipitor – the Fund's policy was produced. Unsatisfied with Plaintiffs' document

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<sup>2</sup> In the course of preparing the attached Affidavits, a few additional responsive documents appear to have been located. In light of the parties' discovery stay, the Plaintiffs will address this issue directly with Pfizer.

productions, on September 7, 2007, Pfizer moved to compel the production of more than seventy categories of documents [Dkt 133] (“Motion to Compel”).

The documents Pfizer seeks generally fall into five categories: (i) documents relating to each Plaintiff’s process for reimbursing participants for Lipitor, including, *inter alia*, payments made for Lipitor, documents relating to Lipitor’s placement on a formulary, and documents relating to any restrictions imposed by the Funds for the reimbursement of Lipitor prescriptions (including denials of Lipitor reimbursement claims); (ii) participant-specific medical information, including, *inter alia*, documents relating to any off-label prescriptions written for Lipitor (including the names of physicians who prescribed Lipitor for off-label uses), documents relating to any off-label payments made for Lipitor (including copies of prescriptions written for off-label uses of Lipitor), participant’s cardiac risk profiles and several other categories of patient-specific medical information; (iii) communications between Plaintiffs and any third-party regarding Lipitor and/or this lawsuit; (iv) documents concerning the operation of the Funds; and (v) documents concerning any allegations in the First Amended Complaint (“FAC”).

Many of the documents the Order compels just do not exist. They must be *created* by Plaintiffs after they receive patient specific medical information from non-parties – often members’ physicians. For example, in order to produce documents identifying physicians that prescribed Lipitor for an off-label use (Order at 7), Plaintiffs would need to request patient medical records from physicians. If the physicians produce the requested records, Plaintiffs must then analyze those records to determine whether particular participants were prescribed Lipitor for an off-label use. Only after such request, collection, and analysis can Plaintiffs create a report showing – as is compelled by the Order – names of physicians that prescribed Lipitor for an off-label use. The same analysis is required for many other requests compelled by the Order. See Order at 7 (noting that Pfizer’s requests demanded, *inter alia*, “documents identifying the name of any physician who prescribed Lipitor for an off-label purpose (Doc. Req. 7) . . . documents reflecting payments by Plaintiffs for Lipitor prescribed for an off-label purpose from 2002 to present (Doc. Req. 9). . . .”).<sup>3</sup> Other documents, such as “documents relating to meetings

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<sup>3</sup> At oral argument, Magistrate Judge Brown was advised of the need to obtain medical records before any off-label prescriptions/payments could be identified. See Exhibit B at 8-9 (8/15/07 Hr’g Tr.) (By Mr. Grygiel: “Well, you can’t get to what’s allegedly improperly off label until you get all the medical records.”).

where a presentation about Lipitor was made to the Plaintiffs or their employees (Doc. Req. 56),” Order at 9, are, if they exist, not within Plaintiffs’ care, custody or control.

Before the Magistrate Judge below, Pfizer offered no evidence whatsoever establishing that *any* of the more than seventy categories of documents that Pfizer moved to compel actually exist, let alone that they are in Plaintiffs’ custody or control. Pfizer served no fewer than 150 interrogatories and more than 1,000 requests for admissions demanding answers and responses to myriad detailed questions and statements. Pfizer served more than 1,000 document requests demanding production of different kinds of documents and reports. *Yet Pfizer never served discovery seeking an inventory of what documents or kinds of documents actually are in Plaintiffs’ possession.* Rather, Pfizer’s entire motion rested on bald assertions that Plaintiffs have, or have control over, the documents it seeks.

**B. Plaintiffs File The SAC to Alter The Theory of Liability and Damages**

Even if Plaintiffs controlled their members’ patient-specific information – and they do not – based on the theory of liability articulated in the SAC, such information has virtually no relevance here. Plaintiffs expressly sought leave to file the SAC after Magistrate Judge Brown’s rulings made proving the theory pled in the FAC impractical if not impossible.

As detailed in a number of Plaintiffs’ prior filings, Plaintiffs intended to prove damages under the FAC based on commercially available data, internal Pfizer data demonstrating and quantifying the results of Pfizer’s illegal off-label marketing efforts, and statistical/econometric modeling establishing a relationship between Pfizer’s illegal marketing and a corresponding increase in Lipitor sales. On Pfizer’s motion to compel responses to an interrogatory, Magistrate Judge Brown rejected Plaintiffs’ proposed approach to establishing damages and on July 19, 2007, ordered that by August 20, 2007, Plaintiffs identify each allegedly off-label Lipitor prescription paid for by one of the funds to be selected by Plaintiffs. *See* [Dkt 98]. *See also* [Dkt 166] at 2. Plaintiffs identified the Plumbers & Pipefitters Local Union 630 Welfare Trust Fund (“Plumbers & Pipefitters”) as the test fund.

Plumbers & Pipefitters did not have the medical records needed to comply with the July 19 Order. To comply, Plumbers & Pipefitters engaged in an expedited and extraordinarily burdensome campaign to contact individual doctors and obtain the requested records from them. This process was very time consuming and laborious. Plaintiffs were asked repeatedly to explain the need for reviewing individual participant’s medical histories and the basis for providing them

without individual participants' releases. In the end, Plumbers & Pipefitters was at the mercy of physicians. If physicians refused to produce documents, Plumbers & Pipefitters had no ready and practical means to compel their production.

Replicating this time-consuming, labor intensive and largely unsuccessful (Plumbers & Pipefitters obtained only about 50 medical files of the approximately 150 requested) process for the remaining funds (let alone for all members of the class) simply was not realistic. Accordingly, on August 28, 2007, Plaintiffs sought leave to file the SAC. [Dkt 113.] Expressly filed to avoid the burden imposed by Magistrate Judge Brown's discovery rulings, the SAC significantly changed Plaintiffs' theory of damages. The FAC had premised liability on increased *sales* of Lipitor for off-label uses of the drug. In contrast, the SAC pleads that Pfizer increased the *price* of Lipitor through a host of deceptive schemes that caused Plaintiffs to pay artificially inflated prices for Lipitor regardless of its use. While the motion for leave to file the SAC was pending, on August 28, 2007, Magistrate Judge Brown ordered Plaintiffs to provide the information provided by Plumbers & Pipefitters for the remaining funds by September 26, 2007.

On September 3, 2007 this Court granted Plaintiffs' Motion for Leave to File the SAC, and entered a briefing schedule for Pfizer's motion to dismiss the SAC. [Dkt 126.] As Plaintiffs' counsel described to the Court during an August 28, 2007 hearing before Magistrate Judge Brown, the SAC greatly streamlines the case by simplifying Plaintiffs' theory of damages. *See* [Dkt 166 at 3.] The SAC alleges only that Pfizer's false and misleading promotion of Lipitor resulted in Lipitor's price being higher than it would have been without such promotion. Damages under the SAC are, therefore, the difference between the price Plaintiffs paid for Lipitor and the price they would have paid had Lipitor's price not been wrongly inflated by Pfizer's false statements and material omissions. The administrative burdens and privacy implications of Magistrate Judge Brown's orders now greatly outweigh the relevance, if any, of participant-specific medical related discovery. On September 10, 2007, Plaintiffs moved to modify the Court's August 28, 2007 order. [Dkt 136.] On November 14, 2007, Magistrate Judge Brown denied Plaintiffs' motion to modify discovery. *See* [Dkt 166 at 8.] The November 14, 2007 order concluded that the identification of each off-label payment made by each fund was still within the scope of Rule 26 and that the production of such information was not overly burdensome. *See id.* at 6-8. Plaintiffs filed Amended Objections to Magistrate Judge Brown's

November 14 order on November 29, 2007. Plaintiffs' Objections are fully briefed and are pending before the Court.

Because the Order erroneously compels production of documents that: (i) are not in Plaintiffs' possession or control; and (ii) provide little, if any, benefit to Pfizer under the theory of liability and damages in the operative complaint, the Order must be reversed.

### ARGUMENT

**THE ORDER VIOLATED APPLICABLE LEGAL PRINCIPLES BECAUSE: (i) THE ORDER ERRONEOUSLY PLACED THE BURDEN ON PLAINTIFFS OF PROVING NON-CONTROL OF DOCUMENTS THAT PFIZER MOVED TO COMPEL; AND (ii) THE ORDER FAILED TO CONSIDER, AS IS REQUIRED UNDER RULE 26, THE BURDEN OF COMPLIANCE GIVEN THE THEORY OF LIABILITY PLED IN THE OPERATIVE COMPLAINT**

Fed. R. Civ. P. 72(a) provides "[w]ithin 10 days after being served with a copy of the magistrate judge's order, a party may serve and file objections to the order. . . . The district judge to whom the case is assigned shall consider such objections and shall modify or set aside any portion of the magistrate judge's order found to be clearly erroneous or contrary to law."<sup>4</sup> "The 'clearly erroneous' standard applies to factual findings and discretionary decisions made in connection with non-dispositive pretrial discovery matters." *F.D.I.C. v. Fidelity & Deposit Co. of Maryland*, 196 F.R.D. 375, 378 (S.D. Cal. 2000). Where a magistrate judge's findings are based on legal conclusions and not findings of fact the "clearly erroneous standard does not apply" and the scope of review "is plenary." *See e.g., Jernryd v. Nilsson*, 117 F.R.D. 416, 417 (N.D. Ill. 1987). *See also Fidelity Deposit*, 196 F.R.D. at 378 ("The 'contrary to law' standard, however, permits independent review of purely legal determinations by the magistrate judge"). The Order is erroneous for two primary reasons.

First, the law clearly places the burden of establishing control over documents squarely on the party moving to compel production. *See Sparks Tune-Up Centers, Inc. v. Panchevre*, No. 90 C 4369, 1991 WL 101667, at \*3 (N.D. Ill. June 4, 1991) ("the party which brings the motion to compel has the burden of establishing that the non-movant has control of the requested documents") (citing *Norman v. Young*, 422 F.2d 470, 473 (10th Cir. 1970)); *Technical Concepts*,

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<sup>4</sup> Because the Order was served on Plaintiffs by mail, Plaintiffs are entitled to rely Fed. R. Civ. P. 6(e). *See Lerro v. Quaker Oats Co.*, 84 F.3d 239, 242 (7th Cir. 1996) (Rule 6(e) applies to objections under Rule 72).

*L.P. v. Continental Mfg. Co.*, No. 92 C 7476, 1994 WL 262119, at \*1 (N.D. Ill. June 10, 1994) (“The burden of showing that a party is in control of requested documents falls upon the party which brings the motion to compel”). The Order cites no case to the contrary. Contradicting settled law, the Order erroneously placed the burden of establishing non-control of the documents on Plaintiffs. Specifically, the Order replaced the appropriate analysis with an analysis based on what Magistrate Judge Brown “expected” would be under Plaintiffs’ control. See Order at 9. Settled case law establishes that, as the party seeking to compel production, Pfizer – not Plaintiffs – bore the burden of proving Plaintiffs’ control over the documents Pfizer sought to compel.

Second, the Order disregards Rule 26’s limitation on discovery by failing to perform the required balancing of whatever tangential relevance this information may have against the enormous burden that Plaintiffs would bear if compelled to try to get this patient-specific data.

**A. The Order Requires Production Of Materials That Are Not Within The Possession, Custody Or Control Of Plaintiffs**

The Order erroneously compels the production of documents that Magistrate Judge Brown “expects” would be in Plaintiffs’ possession without requiring Pfizer to carry its burden of establishing control. See Order at 9. Plaintiffs cannot be compelled to produce documents that they neither possess nor control. See *Sparks Tune-Up Centers, Inc.*, 1991 WL 101667, at \*3 (“A party cannot be required to permit inspection of documents or things that he does not have and does not control.”) (citing Wright & Miller, Federal Practice & Procedure: Civil, § 2210 (1970)); *Calhoun v. Volusia County*, No. 604-CV-106-ORL-31DAB, 2007 WL 1796259, at \*1 (M.D. Fla. June 20, 2007) (“the Court cannot compel production of documents that do not exist”).<sup>5</sup> Moreover, if Plaintiffs obtain participants’ medical files – for the requests premised on patient medical records – Plaintiffs must create reports in order to comply with the Order. Documents readily showing, for example, off-label prescriptions of Lipitor do not exist in any form. The federal rules do not permit one party to force another to create documents that do not already exist. See *Rockwell Intern. Corp. v. H. Wolfe Iron and Metal Co.*, 576 F. Supp. 511, 513

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<sup>5</sup> The Order cites nine document requests identified in Pfizer’s Motion to Compel and erroneously concludes that Plaintiffs “previously agreed” to produce these documents. See Order at 7-8 (citing Req. Nos. 7-10, 12, 19, 21, 29, 30). In response to each of these requests, Plaintiffs agreed to produce documents *to the extent responsive documents were within Plaintiffs’ possession, custody or control*. Plaintiffs cannot produce documents they do not possess or control.

(D.C. Pa. 1983) (a party “cannot be compelled [under Rule 34] to create, upon the request of . . . [an opponent], documentary evidence which is not already in existence in some form”); *Gray v. Faulkner*, 148 F.R.D. 220, 223 (N.D. Ind. 1992) (“Of course, ‘[i]f a document or thing does not exist, it cannot be in the possession, custody, or control of a party and therefore cannot be produced for inspection.’” ) (quoting 10A Federal Procedure, Law Ed. § 26:381, pp. 52-53 (1988)).

Plaintiffs are third-party payors that pay for prescription medications for their members and their members’ dependents. Plaintiffs are not physicians. Nor are they document repositories for participant medical or other prescription payment information.<sup>6</sup> To the extent the Order compels the production of participant-specific medical related documents, such documents are held by the Funds’ participant’s physicians. Other documents compelled by the Order, such as presentations about Lipitor, are not within the Plaintiffs’ care, custody or control.

Pfizer’s Motion to Compel presented no evidence establishing that Plaintiffs, in fact, possess or control the documents Pfizer seeks, or that such documents even exist. Pfizer could have served an interrogatory asking Plaintiffs to identify or provide an inventory detailing the documents they control. Pfizer did not. Accordingly, Pfizer was unable to offer any evidence *whatsoever* establishing that each Plaintiff actually possessed responsive documents that have not been produced.

In fact, the record shows the opposite. To obtain medical records from the Plumbers & Pipefitters’ participants’ physicians, Plaintiffs’ counsel sent letters to each physician that prescribed Lipitor asking the physicians to provide Plaintiffs with the participants’ records. *See* [Dkt 106 attachment A]. Pfizer argued that the letters were biased and asked the Court to let Pfizer participate in drafting the records request letter. *See* Exhibit B at 31 (8/15/07 Hr’g Tr.) (“I will take as much time as necessary to work with Mr. Grygiel on a letter that we can jointly send or he can send. . . .”). *See also id.* at 32 (ordering parties to meet and confer over the language of letters requesting medical records). Pfizer’s ability to interject itself – as an adverse party – into the process of requesting records all by itself demonstrates that Plaintiffs do not have the ability

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<sup>6</sup> As explained in the attached affidavits, in certain limited circumstances some Plaintiffs may receive medical records. However, in the few instances where medical records are received, such records are received for limited purposes, such as a participant appeal of a denial of benefits. Plaintiffs do not receive, maintain or control the sensitive patient information needed to determine participants’ cardiac risk profiles and/or off-label uses of Lipitor.

to demand the necessary documents as a matter of right. If Plaintiffs had the ability to demand such documents, a letter writing campaign – with Pfizer’s input – would have been unnecessary. Plaintiffs do not have the ability to simply pick up a phone and demand documents. Pfizer, unsurprisingly, made no showing that Plaintiffs control participants’ medical records; the record, in fact, proves the opposite.

The Order turns the applicable burden of proof on its head: “Plaintiffs complain that they do not ‘possess or control much of the individual physician and patient information Pfizer seeks. (Pls.’ Opp’n at 7-8). That, of course, begs the question of what information Plaintiffs *do* possess or control. Plaintiffs’ Opposition provides the court no affidavits or even descriptions of what information Plaintiffs maintain about the Plans they administer, the benefits they provide, and the prescriptions for which they have paid.” Order at 9 (emphasis in original). This observation wholly ignores that Plumbers & Pipefitters’ (and Pfizer’s) experience in seeking responsive documents from individual physicians conclusively demonstrated that Plumbers & Pipefitters did *not* have “custody or control” over the documents Pfizer seeks. This observation also misses the key point that whether Plaintiffs submitted affidavits or any evidence whatsoever establishing “non-control” is legally irrelevant. Pfizer bore the burden, as the movant, to submit evidence that Plaintiffs actually had custody and control over the documents it demanded. *See Sparks Tune-Up Centers*, 1991 WL 101667, at \*3; *Technical Concepts*, 1994 WL 262119, at \*1 (N.D. Ill. June 10, 1994) (“The burden of showing that a party is in control of requested documents falls upon the party which brings the motion to compel”).

At oral argument, when it became apparent that Magistrate Judge Brown was inclined to relieve Pfizer of its burden of proof, Plaintiffs’ counsel offered to provide affidavits to Judge Brown (“we’d be happy to provide an affidavit if that’s necessary” (Exhibit C at 20 (9/26/07 Hr’g Tr.)). Plaintiffs’ counsel made representations of burdensomeness as an officer of the Court with the full understanding that such representations were made in accordance with Rule 11. *Id.* at 20. No affidavits were requested.

Rather than accepting Plaintiffs’ counsel’s representations, however, Magistrate Judge Brown ignored the applicable burden of proof and criticized Plaintiffs for not offering “evidentiary support in the form of an affidavit or declaration” establishing the burdensomeness of production. Order at 10. But whether Plaintiffs provided evidence of burdensomeness is

completely irrelevant to whether Pfizer carried *its burden* of proving that Plaintiffs had custody and control over the documents the production of which it moved to compel.

Although legally not required to do so, and although Pfizer never served an interrogatory seeking identification of what documents Plaintiffs actually control, Plaintiffs provide herewith affidavits from each of the named Plaintiffs documenting what documents they actually possess, and what kinds of documents they do not have. *See e.g.*, Exhibits D1-D11. As declared in these affidavits, Plaintiffs have provided Pfizer with several responsive documents, including, Lipitor payment information, documents governing the operation of the Funds, summary plan descriptions, documents received from certain Fund's advisors and documents relating to a program by one Fund to restrict Lipitor payments.<sup>7</sup> *See id.* Plaintiffs have not provided – because such documents do not exist or are not in Plaintiffs' possession or control – documents relating to, *inter alia*, off-label use/payment information for Lipitor, participant health profiles, documents regarding the placement of Lipitor on formularies and presentations about Lipitor.<sup>8</sup>

Plaintiffs' claims that they do not control the documents compelled by the Order are not made in a vacuum or without the experience of actually seeking to obtain such documents. Plaintiffs' counsel provided the following example as one of the many hurdles faced by Plaintiffs when they attempted to secure Plumbers & Pipefitters' members' medical records during a hearing before Magistrate Judge Brown:

One other quick point, Your Honor, and then I'm done. Mr. Cheffo said: Well, they can do it. It's not burdensome. Look at the Florida case. Look at the letters. Yes, indeed, those letters said we have the ability to do this, to get these documents, and a lot of doctors' offices called and said: *No, you don't.*

Exhibit C at 38 (9/26/07 Hr'g Tr.) (emphasis added).<sup>9</sup> *Compare id.* with Order at 10 (concluding that Plaintiffs' burdensome arguments “lacks any evidentiary support”). Accordingly, contrary to Magistrate Judge Brown's expectation that Plaintiffs control all the documents ordered to be produced, the examples offered by Magistrate Judge Brown illustrate the *lack* of control that

<sup>7</sup> These documents are responsive to Doc. Req. Nos. 1, 8, 15-16, 20, 27, 31, 34, 35, 37, 52, 61, 63-64, 81-82, as identified in Pfizer's Motion to Compel. *See* Motion to Compel at 5-9.

<sup>8</sup> *See e.g.*, Motion to Compel at 5-9 (Doc. Req. Nos. 2-4, 7, 9, 17-19, 22-24, 26, 28-30, 32-33, 38-43, 45-47, 56, 60, 65, 67-68, 71-72, 76-77, 79-80, 84-85).

<sup>9</sup> *See also Technical Concepts*, 1994 WL 262119, at \*1 (control over documents requires a “legal right to obtain the documents *on demand*.”) (emphasis added).

Plaintiffs have over those documents. In any event, the law does not charge Plaintiffs with the burden of establishing that they do not control the documents demanded by Pfizer. The burden was squarely on Pfizer to establish Plaintiffs' control – and Pfizer failed to introduce any evidence doing so.<sup>10</sup>

**B. Requiring Plaintiffs To Produce Participant Specific Medical Information Is Unduly Burdensome**

Rule 26(b)(2)(C) states, “[T]he court *must* limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that . . . (iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.” (Emphasis supplied.)

Plaintiffs' Amended Objections to Magistrate Judge Brown's November 14, 2007 Order [Dkt 173] and Plaintiffs' Reply in Further Support of its Amended Objections to Magistrate Judge Brown's November 14, 2007 Order [Dkt 188] detail the appropriate analysis under Rule 26 and are incorporated by reference herein. Plaintiffs have no intention of using individual patient prescriptions to establish causation and damages. Based on the theories of liability and damages in the SAC, even if Plaintiffs controlled documents detailing participant specific medical information – and they do not – the burden of requesting, analyzing and creating responsive documents outweighs what little, if any, benefit the documents would provide to Pfizer. *See* Fed. R. Civ. P. 26(b)(2)(C)(iii). *See also Patterson v. Avery Dennison Corp.*, 281 F.3d 676, 681 (7th Cir. 2002) (Rule 26(b)(2) “empowers district courts to limit the scope of discovery if ‘the discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive.’”).

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<sup>10</sup> To the extent there is any ambiguity over the issue of Plaintiffs' control over the documents compelled by the Order, the affidavits submitted herewith show which documents Plaintiffs control and which they do not. *See* Exhibits D1-D11. As illustrated by the attached affidavits, Plaintiffs do not possess or control the patient specific medical records compelled by the Order. *See id.* *See also In re Remeron End-Payor Antitrust Litig.*, No. Civ. 02-2007 FSH, Civ. 04-5126 FSH, 2005 WL 2230314, at \*15 n.4 (D.N.J. Sept. 13, 2005) (noting that “End-Payor Plaintiffs and Plaintiff States were unable to obtain a list of potential class members for a direct mail campaign and instead had to *rely* on pharmacies and psychiatrists to forward notices to their customers and patients”) (emphasis added). Accordingly, ordering the production of documents that Plaintiffs do not possess or control cannot be justified.

Rejecting Plaintiffs' claims of undue burden out of hand, the Order concludes that the patient specific medical information compelled by the Order is relevant to the "issues of both causation and damages." Order at 11. The Order's insistence that the compelled documents are absolutely necessary in this case is incorrect. First, the decision in *In re Neurontin Marketing and Sale Practices Litig.*, 244 F.R.D. 89 (D. Mass. 2007), demonstrates that individual patient specific medical information is not a prerequisite to establishing causation and damages in a case seeking damages for overpaying for a prescription drug. Second, the SAC is seeking damages for each and every payment of Lipitor - not simply off-label payments. Thus, individual patient records have little, if any, relevance to that damages claim. Finally, HIPPA and state privacy laws impose an independent hurdle to complying with the Order.

**1. Courts Recognize That Individual Patient Records Are Not a Prerequisite to Proving Causation and Damages In a Case Alleging Overpayment for Prescription Drugs**

The Order's holding that individual patient information is relevant to the issues of causation and damages (Order at 11) is undermined by rulings of district courts in similar lawsuits. In *Neurontin*, Judge Saris considered a motion to certify a class of consumers and third-party payors that alleged injuries because of payments made for off-label prescriptions of Neurontin (another Pfizer drug). Addressing causation and injury, Judge Saris noted that the defendants – like Pfizer here – argued that individual proof of causation and damages was necessary. *See Neurontin*, 244 F.R.D. at 109 ("defendants contend that certification is inappropriate because plaintiffs cannot prove causation or injury on a class-wide basis. Instead, defendants argue, plaintiffs must establish through individualized inquiries. . . ."). Judge Saris rejected that argument. *Id.* at 111. Judge Saris accepted plaintiffs' econometric statistical analysis, which relied on information produced by the defendants and third-parties, to prove causation and injury. Explaining plaintiffs' expert's methodology, the court stated, "[plaintiffs' expert] will rely on extensive sales and promotional data maintained by defendants, as well as information from various other sources, including independent pharmaceutical data and consulting companies like IMS Health and Verispan, which closely track pharmaceutical sales and promotions." *Id.* Accepting the *Neurontin*-plaintiffs' expert's approach, Judge Saris concluded that plaintiffs' expert's "proposed methodology is a plausible way of determining aggregate class-wide liability, and defendants have identified no fundamental flaws now

appearing in her proposal to calculate aggregate damages.” *Id.* Other courts have also expressed a willingness to rely on statistical modeling in third-party payor cases. *See In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571, 577 (E.D.N.Y. 2007) (individualized proof of off-label payments is not a prerequisite to proving damages in third-party payor suits alleging overpayment for prescription drugs). As Judge Weinstein stated in *Zyprexa*, “[b]ased on expert reports and available modes of economic analysis, a trier could determine that Zyprexa would have-or would not have-been sold for a reasonably precise computable lesser amount than it was sold for were it not for Lilly’s alleged fraud.”<sup>11</sup> *Id.* at 577. *See also id.* at 578-79 (“Defendant argues that plaintiffs’ use of aggregate proof, rather than individualized proof, to establish reliance is impermissible. This assertion is without merit”). The Order addresses neither *Neurontin* nor *Zyprexa*.<sup>12</sup>

## 2. Producing Patient Data Would Be Unduly Burdensome Because It Impinges On The Privacy Of Plaintiffs’ Beneficiaries

Producing private medical records of Plaintiffs’ beneficiaries, including disclosure of participant names and dates of birth, is also unduly burdensome because it unnecessarily violates the privacy of third parties, who neither brought nor are parties to this litigation.<sup>13</sup> In *Neurontin* the court held that producing patients’ medical records would be unduly burdensome:

After hearing, I conclude that the burden, expense and invasion of privacy of the proposed discovery outweighs its likely benefit. *See* Fed. R. Civ. P. 26 (b)(2) . . . If either party intends to call a treating physician to give an opinion on effectiveness, sanitized patient records shall be produced to the extent the physician is relying on his experience with treating that patient (as opposed to a clinical trial).

<sup>11</sup> Further undermining the need for individual patient-by-patient information relating to Lipitor is that even if Lipitor were properly prescribed, third-party payors are still entitled to recover overpayments. *See Zyprexa*, 493 F. Supp. 2d at 578 (“While it can be assumed for purposes of this motion that the drug was properly prescribed, payers may recover the difference between the price they paid for Zyprexa and the price they would have paid for Zyprexa but for Lilly’s alleged fraud.”).

<sup>12</sup> Both opinions were cited to Judge Brown in Plaintiffs’ Opposition to Pfizer’s Motion to Compel Plaintiffs to Provide Documents, Unredacted Claims Records, and Responses Concerning Pfizer’s Proprietary Materials [Dkt 140] at pages 6 and 11.

<sup>13</sup> Obtaining and analyzing patient-specific medical records is necessary to comply with the Order. Without patient records, Plaintiffs cannot determine which Lipitor payments were made for off-label prescriptions.

See Order, *In Re Neurontin Marketing, Sales Practices*, No. 1:04-cv-10981-PBS (D. Mass. filed Sept. 27, 2006) (Electronic Order attached hereto as Exhibit E). See also *Riley v. Walgreen Co.* 233 F.R.D. 496, 501 (S.D. Tex. 2005) (“Patient prescription drug orders and medication records contain highly sensitive and personal information . . . Given the extremely sensitive information at issue, the court agrees that both redaction of names and a confidentiality agreement are appropriate.”) Here, just as in *Riley*, the privacy concerns of beneficiaries far outweigh the importance of their medical records to this litigation.

The Order also erroneously concludes that non-parties to this action cannot rely on HIPPA and state privacy laws to resist production of patient specific medical information. Order at 10-11. The third parties holding the records the Order compels to be produced are located in no fewer than ten different states. These medical providers are subject not only to HIPPA disclosure restrictions, but also to state privacy regulations that are – in some cases – more restrictive than HIPPA. See *Remeron*, 2005 WL 2230314, at \*15 n.4 (improperly producing medical records in violation of HIPPA “may subject the provider to civil and/or criminal penalties [under HIPPA].”). Assuming that the Order protects disclosing parties from liability under HIPPA, the Order – which is directed to Plaintiffs – does not protect third-parties from any liability if they disclose protected information in violation of their respective state’s privacy laws. The Order responds to this concern by citing to the Seventh Circuit’s decision in *Northwestern Mem’l Hosp. v. Ashcroft*, 362 F.3d 923 (7th Cir. 2004) (Order at 10-11) and concluding that the Seventh Circuit’s precedent completely moots Plaintiffs’ concern. That application of *Ashcroft* is incorrect.

In *Ashcroft*, the Seventh Circuit addressed whether a subpoena recipient, who moved to quash the subpoena, was entitled to rely on Illinois law to withhold the production of certain medical records. See *id.* See also *National Abortion Fed’n v. Ashcroft*, No. 04 C 55, 2004 WL 292079, at \*2 (N.D. Ill. Feb. 6, 2004) (noting that Northwestern moved to quash), *aff’d*, *Ashcroft*, 362 F.3d 923. *Ashcroft* did not address the broader concerns Plaintiffs raise here, namely, how physicians can be given assurances that their voluntary disclosure of medical records does not – as a matter of law – run afoul of their obligations under their respective states’ privacy laws in the absence of a court-issued subpoena or a patient-executed release. Moreover, unlike *Ashcroft*, where the responding party was served with a subpoena, Plaintiffs have no legitimate recourse if physicians do not comply with Plaintiffs’ request for the production of their patients’ medical

records. If forcing physician compliance requires a subpoena or a release signed by a patient, no legitimate argument can be made that Plaintiffs control the information compelled by the Order.<sup>14</sup>

### CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court sustain Plaintiffs' objections to Magistrate Judge Brown's Order.

DATED: January 15, 2008

Respectfully submitted,

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*Lead Counsel for Plaintiffs and Proposed  
 Lead Counsel for the Class*

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<sup>14</sup> Additionally, the Order's conclusion that, under *Ashcroft*, state privacy laws cannot be used by nonparties to resist production of medical records because the Court's jurisdiction is based solely on federal question – and not diversity – jurisdiction (Order at 11 n.4) is incorrect. *Ashcroft* noted that Illinois' privilege "does not govern in federal-question suits." 362 F.3d at 925. Here, the SAC asserts jurisdiction not only under RICO (which would provide a basis for federal question jurisdiction) but also under 28 U.S.C. 1332, based on diversity of citizenship. See SAC ¶21. The Order concludes that diversity jurisdiction is inapplicable here because Pfizer and one Plaintiff are both citizens of New York. Order at 11 n.4. This observation, however, overlooks the "Class Action Fairness Act" which amended Section 1332 to specifically permit diversity jurisdiction where "any member of a class of plaintiffs is a citizen of a State different from any defendant" and where certain other criteria are met. 28 U.S.C. 1332(d)(2)(A) (emphasis added). Accordingly, if the Court's jurisdiction over this action is based on diversity it is unclear whether *Ashcroft* even applies here. Assuming *Ashcroft* is applicable, the Order does not explain how *Ashcroft* applies when third-parties, who are not served with subpoenas, hold the necessary medical records needed to comply with the Order. Thus, whether *Ashcroft* would apply to permit the production of medical records notwithstanding more restrictive Illinois privacy laws has nothing to do with whether Plaintiffs can force physicians in other jurisdictions to disregard the privacy laws of their respective states and produce documents to Plaintiffs for this action.

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**AFFIDAVIT OF SERVICE**

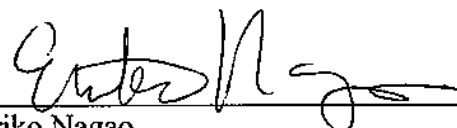
STATE OF NEW YORK     )  
  ) ss.:  
COUNTY OF NEW YORK    )

ERIKO NAGAO, being duly sworn, deposes and says:

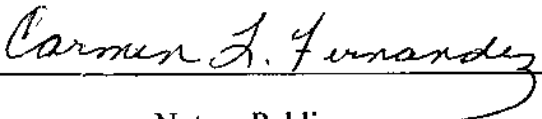
1.     I am over eighteen years of age, not a party to the action and am employed by Skadden, Arps, Slate, Meagher & Flom LLP, Four Times Square, New York, NY 10036.

2.     That on the 6<sup>th</sup> day of June, 2008, I served true copies of the foregoing **Defendant Pfizer Inc's Notice of Motion for Reconsideration of the Minute Order of May 22, 2008, Memorandum of Law and Declaration re: same** by hand to:

**Grant & Eisenhofer  
29<sup>th</sup> Floor  
485 Lexington Avenue  
New York, NY 10017**

  
Eriko Nagao

Sworn to before me this  
6<sup>th</sup> day of June, 2008



Notary Public

CARMEN L. FERNANDEZ  
Notary Public, State of New York  
No. 4905737  
Qualified in Bronx County *Bronx County*  
Certificate Filed in *New York County*  
Commission Expires Sept. 14, 2011